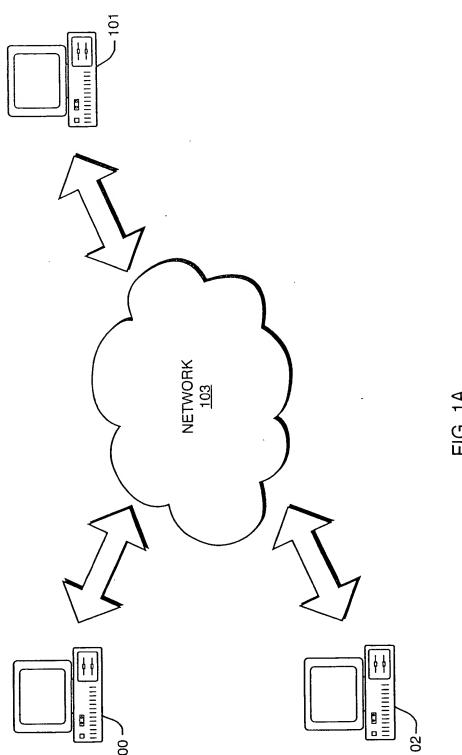
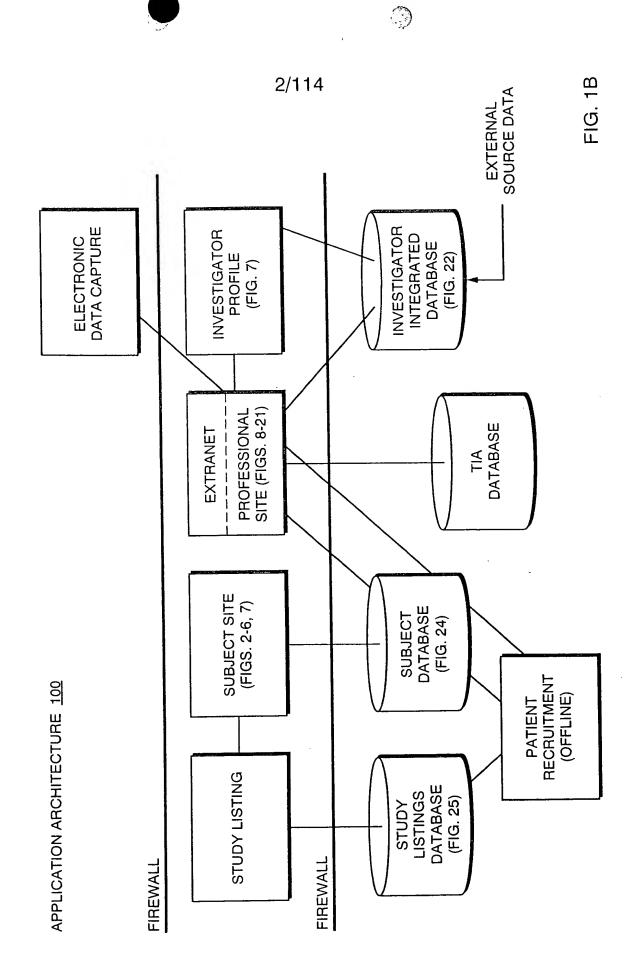




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Search clinical trials $\nabla$	Go Register	<b></b>	t 201	Username Username	Password A-digits	203 — Betyne	Password	your privacy is of the utmost concern to us. For more information, read	As part of the registration process and to protect your privacy, we ask that	<u>a</u>	Your question What is your mother's maiden name? ∇
Search		© Feature Stories	<ul><li> News Archive</li><li> Ask the Expert</li></ul>	About Clinical Trials		Therapeutic Area	© cancer	Neurological Conditions		© Register Now Review Clinica Trials Ask	Questions and More

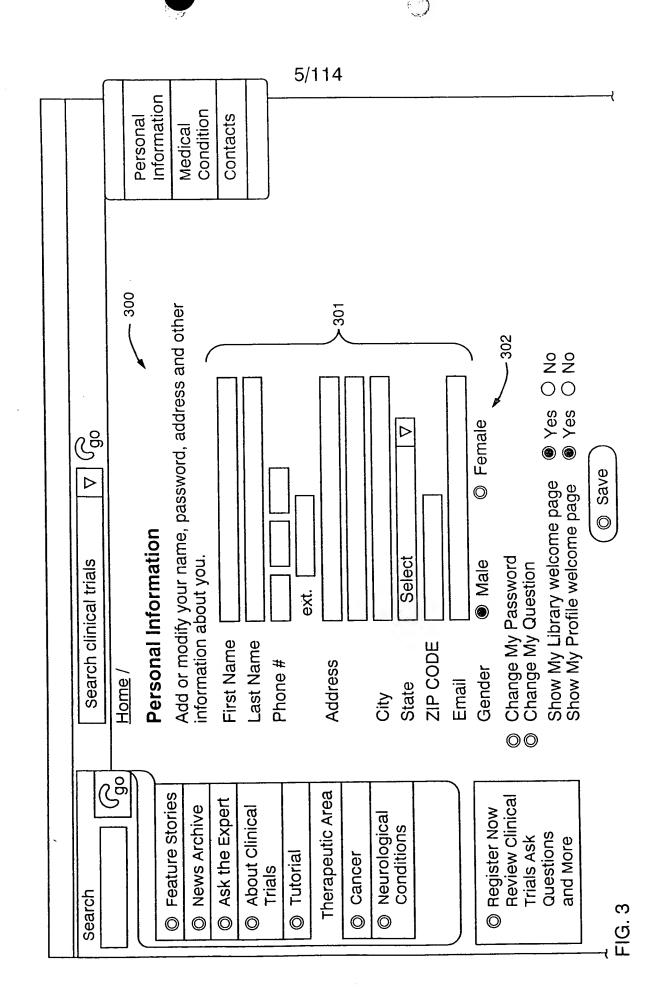
FIG. 2A

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Your answer, up to 45 characters.	Terms of Service Please read the following Terms of Service agreement.	·	© I Agree  Benefits of Registration
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Registered users will benefit from:

- Our comprehensive clinical trial listings get trial information and find out how you can be considered for participation in clinical trials.
- The ability to ask questions of our medical experts.
- Timely, relevant announcements of new trials and drug information. 0
- Exclusive interactive tools, including your own personal library of news information. 0
- Emails informing you of updates to our clinical trial listings, news and information, tailored to your selection. 0
- A personal profile used to optimize your experience. 0



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FIG. 4A

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Rectal Cancer	Henal Cell Carcinoma	Sarcoma	Skin Cancer	Spinal Cord	Malignaricy	Stomach Cancer	T-Cell Lymphoma	Testicular Cancer	Thrombocytopenia	Thymomas	Vaginal Cancer	Vulvar Carcinoma	Wilms' Tumor	

501 CLINICAL Pulmonary/Respiratory Diseases 503 Trauma/Emergency Medicine Pharmacology/Toxicology **Neurological Conditions** Pediatrics/Neonatology Obstetrics/Gynecology Where can you get more information about clinical trials? How are participant's rights and safety protected during a Ophthalmology **Otolaryngology** Rheumatology ره 0  $\bigcirc \bigcirc$ 0 O Introduction: What are clinical trials Immunology/Infectious Diseases Why are clinical trials important?  $\triangleright$ Cardiology/Vascular Diseases Dermatology Plastic Surgery Dental/Maxillofacial Surgery Who pays for clinical trials? Questions you need to ask. **About Clinical Trials** Search Clinical Trials The clinical trial process. Search clinical trials **Nephrology/Urology** Clinical Trials FAQ Gastroenterology Home / About Us Musculoskeletal **Endocrinology** Hematology clinical trial? © Cancer رقی Stories Therapeutic Area Ask the Expert Review Clinical **News Archive** About Clinical Neurological Conditions Register Now Questions Trials Ask and More Tutorial Cancer Trials Search 0 0 0 0 0

FIG. 5A

Common terms used in clinical trials.

# Introduction: What are clinical trials?

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Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the

If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

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Back to top

## Why are clinical trials important?

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

Back to top

### The clinical trial process.

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

Phase I. In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to sometimes severely ill patients will participate in these find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but

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Phase II. In these trials, the safety and effectiveness of an people who have the disease or condition to be treated investigational treatment is studied in larger groups of

Phase III. In Phase III trials, the safety and effectiveness of biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Typically, there are hundreds or thousands of people in a compared with standard treatments in hopes of finding populations of people for whom the drug is intended Phase III trial. Often, the investigational treatment is better ways to help people. The pharmaceutical or an investigational treatment are studied in larger Administration (FDA)

trials. Only after the FDA has determined that the medicine after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and Phase IV. Phase IV trials are also called post-marketing is both safe to use and equivalent or superior to existing physicians and their patients. Phase IV trials take place therapies is it then made available for broader use by efficacy of the drug

Back to top

# How are participant's rights and safety protected during a clinical trial?

The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

Back to top

## Who pays for clinical trials?

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administrate the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.

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Sponsors may pay you to participate in a clinical trial.
 Typically, these fees, when provided, are nominal.

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 Medical care is often provided at no cost to the patients, but they still may be responsible for other expenses such as travel between their homes and the health care facility.

Patients may also have to pay for some medical procedures, tests, or hospital stays if these are considered a part of standard treatment and not part of the clinical trial. Before you enroll, you should determine exactly who pays for what services.

Back to top

# Where can you get more information about clinical trials?

If you or someone you know has a medical problem and is thinking about taking part in a clinical trial, speak to your health care provider first. In taking an active role in the management of your health, you may want to work closely with your provider to find out if a particular clinical trial is right for you.

Back to top

### Questions you need to ask.

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- What is the length of your involvement in the clinical trial? How long will the trial last?
  - Where will you have to go in order to participate in the clinical trial?
- What are the possible treatments you may receive while in the clinical trial?
- possible treatments for this disease? If not, what are your other treatment alternatives? Do the treatment alternatives they provide cover all
  - What procedures are built into the study to keep you safe from harm while you are participating?
- What are the risks and benefits of participating in the clinical trial? If there are risks, what will happen should you have
  - an adverse reaction to the treatment in the study ? What costs may you incur if you participate ?
- Will the treatment be available to you even after the trial? What is their purpose in sponsoring the trial? Where are the funds coming from to conduct this clinical trial has concluded?

You should also feel free to ask any other question about

the trial you want answered

Back to top

## Common terms used in clinical trials.

Clinical trial: A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

Clinical investigator: A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

Coordinator: A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

Food and Drug Administration: The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

Informed Consent: Informed consent is a process that confirms a patient understands the nature of a study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

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Institutional Review Board: An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

Investigational treatment: Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

**Principal investigator:** The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

**Protocol:** A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

Sponsor: The sponsor is the organization that funds a clinical trial and that develops a plan for the research. The organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.

Standard treatment: Standard treatment is a term that refers to approved medical procedures, drugs, tests, or hospitalizations that are a part of the general care considered to be appropriate for certain diseases and conditions. It is the "best treatment" currently known for a given disease. If there are no current treatments shown to be effective against a particular disease, then no treatment would be the standard treatment for that condition.

Back to top

FIG. 5J

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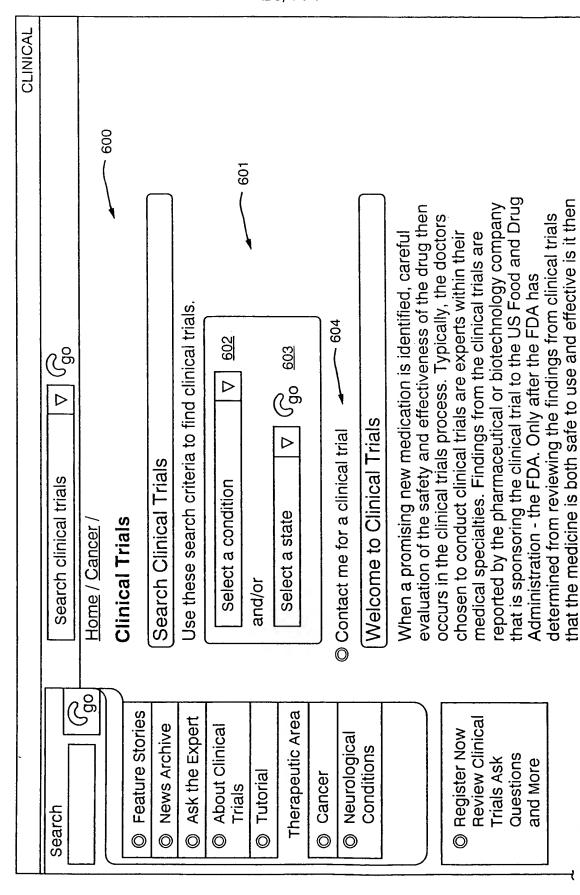


FIG. 6A

made available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

FIG. 6B

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FIG. 6C

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FIG. 6D

Search clinical trials $\nabla$	Register Step 1 of 3	Welcome!  To register with we invite you to compute the following questionnaire about you and your health. This should take approximately 5 minutes to will use the information to present you with new medical	id clinical tri	Your privacy and security are very important to us; therefore we encourage you	to leview our rivacy & decandy i oney:	Choose Your Username and Password	Please choose a username		Choose your reminder question What is your mother's maiden name?   $\nabla$   Please enter your answer to the	Are you seeking information for yourself, or for someone else?	I am seeking information for myself	I am seeking information for someone else	Continue
Search	(S)	© Feature Articles © Medical News	Ask the Expert	<ul><li>All About Clinical Trials</li></ul>		Therapeutic Area	© Cancer	<ul><li>Neurological Conditions</li></ul>		© Register Now	Trials Ask	Questions	

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FIG 6F

Conditions  A sk the Expert  A sk the Expert  A sk the Expert  A sk the Expert  A shout  Clinical Trials  Conditions  A labout  Clinical Trials  Conditions  Condi
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1G. 6F

Alopecia (Hair Loss) Cancer: Prostate Seizures (Epilepsy)

My Conditions:

I do not want to receive information by e-mail. 

**Medical Conditions** By completing this section, you will help us to provide you with information that meets your interests.

I am interested in the following conditions \* (you may choose more than one):

< Remove Add > Alopecia (Hair Loss) Medical Conditions: \* Acne AIDS/HIV Allergies

Continue

FIG. 6G

Step 3 of 3 By selecting "I Accept", you are accepting the Terms and Conditions above and will become a registered user. 4 Please read the following Terms and Conditions Agreement. I would like to receive information about my conditions: I Do Not Accept Send me News and New Medical Therapies Send me News and New Medical Therapies Send me News and New Medical Therapies TERMS AND CONDITIONS Send me Člinical Trial Opportunities Send me Clinical Trial Opportunities Send me Clinical Trial Opportunities رهي Do not send me information Do not send me information Do not send me information  $\triangleright$ I Accept Information Request **Terms and Conditions** Alopecia (Hair Loss):
Send me Clinical
Send me News an
Do not send me in Seizures (Epilepsy):
Send me Clinical
Send me News a Search clinical trials Cancer - Prostate: رقی Feature Articles Therapeutic Area Review Clinical Ask the Expert Medical News **Clinical Trials** Register Now Neurological Conditions Questions **Trials Ask** and More All About Tutorial Cancer Search 0 0 0 0 0 0

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FIG. 6H

Search clinical trials $\nabla$	Registration Complete	Thank you for registering with us.	Your request to receive information about the conditions you selected is being processed; you should receive updates periodically.	As a result of your interest in clinical trial opportunities, we would like to ask	questions are similar to what a doctor, or other medical professional would	ask you when you are being screened for participation in a specific cliffical trial. This information is important in determining your possible preliminary	eligibility for a specific clinical trial.	Please take a few more minutes to answer the next set of questions, and keep in mind that these are optional. If you do not have time to complete the	additional questions right now, you may update your profile the next time you login to acurian.com. Would you like to continue?	Yes, Continue No, Return to Previous Activity	
Search	8	Seature Articles	<ul><li>Medical News</li><li>Ask the Expert</li></ul>	All About     Clinical Trials		Therapeutic Area	© cancer	<ul><li>Neurological Conditions</li></ul>		© Register Now Review Clinical Trials Ask Questions	and More

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FIG. 6J

Search	Search clinical trials $\nabla$
8	Health Habits (Optional) Step 2 of 5
© Feature Articles	It is often important to know your health habits when presenting you with possible clinical trial opportunities.
<ul><li>Medical News</li><li>Ask the Expert</li></ul>	How often do you exercise?
<ul><li>All About</li><li>Clinical Trials</li></ul>	<ul><li>Once a week</li><li>Twice a week</li></ul>
© Tutorial	<ul><li>Three times a week</li><li>Four or more times a week</li></ul>
Therapeutic Area	Daily
	How often do vou visit vour primary care physician?
© Neurological Conditions	© Once a year
	<ul><li>Every month</li><li>I do not have a primary care physician</li></ul>
© Register Now Review Clinical	Do you smoke cigarettes?  No, I have never smoked
Questions and More	<ul><li>Yes, daily</li><li>Yes, occasionally</li></ul>

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## DYWELER CEUELL

Search	Search clinical trials $\nabla   \Theta_0 $
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	A clinical trial is a carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.
Ask tile Expert     All About     Clinical Trials     Tutorial	The following questions ask about your experience and interest in participating in clinical trials. These questions are to help us know how many members of ours have participated in clinical trials before.
Therapeutic Area  Cancer  Neurological Conditions	How many clinical trials have you participated in ?
© Register Now Review Clinical Trials Ask Questions and More	How interested would you be in participating in a clinical trial for a drug that might be used to treat any medical condition(s) you may have?  © Very interested  © Somewhat interested  © Not Sure  © Not interested

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If interested in clinical trial participation how far would you be willing to travel to participate in a clinical trial?

- 1 10 miles11 50 miles51 100 milesMore than 100 milesAny distance

Save and Continue

Save and Return to Previous Activity

FIG. 6N

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questions may help determine if you may potentially qualify for a specific clinical right. Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the condition(s) for which you have been diagnosed. Your answers to the following Listed below are the conditions you selected earlier in the questionnaire. After opportunities. When you are screened for a clinical trial, the doctor at the trial you answer questions about each condition, a check mark will appear to the Step 4 of 5 Earlier in the registration process, you expressed interest in clinical trial site needs to know more information about your health and the medical Questionnaire Complete Save and Return to Previous Activity 回口回 Save and Continue رگ ا next time you login to acurian.com.  $\triangleright$ Alopecia (Hair Loss) Seizures (Epilepsy) Cancer: Prostate Clinical Trial Questions Condition Search clinical trials رهی Eeature Articles Therapeutic Area Review Clinical Ask the Expert Medical News Register Now Clinical Trials Neurological Conditions Questions **Trials Ask** and More All About Cancer Search 0 0 0 0

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FIG. 60

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FIG. 6P

Search clinical trials ∇ Go  Thank You	/ Your message was sent successfully. Thank you for contacting us. Your comments will help us serve you better.	Return to Previous Activity	
Search Go	© Feature Articles © Medical News	<ul> <li>♦ All About Clinical Trials</li> <li>♦ Tutorial Therapeutic Area</li> <li>♦ Cancer</li> <li>♦ Neurological Conditions</li> <li>♦ Register Now Review Clinical Trials Ask Questions</li> </ul>	

FIG. 60

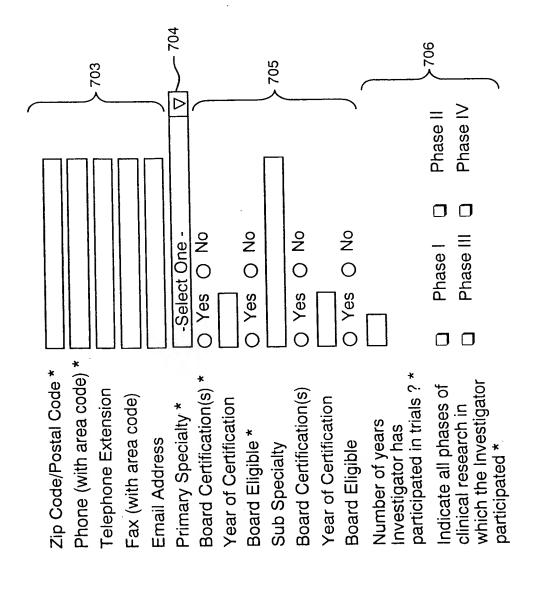
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Search clinical trials $\nabla \left  \bigcirc \bigcirc \right $	o Home / Knowledge Center /	Welcome to My Library	Here's vour chance to create a library of your very own. My	Library is where you can store all kinds of information	found throughout the site. Whether it s cliffical trial information, abstracts on news articles, drug information,	perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as	long as you choose to keep them there. All you nave to do	the site.	In addition, you can type in personal notes along with the	items you save. We will not access, use, or review your personal notes for any reason.	If you'd like to go directly to one of the five sections, select a link below:	<ul><li>News</li><li>Drug Information</li></ul>	○ Clinical Trials ○ Ask The Expert	Fe	☐ Do not show this page again.
Searc	Home /	Welco	Here's	Library	found t	perspe links to	long as	the site	In addi	items y person	If you'c a link h	O News O Drug I	© Clinica © Ask T	Ë	
Search	(%)		© Feature Stories	News Archive	Ask the Expert	<ul><li>About Clinical Trials</li></ul>		Therapeutic Area	⊚ cancer	<ul><li>Neurological Conditions</li></ul>		© Register Now	Trials Ask	Questions and More	

FIG. 6R

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FIG. 7A

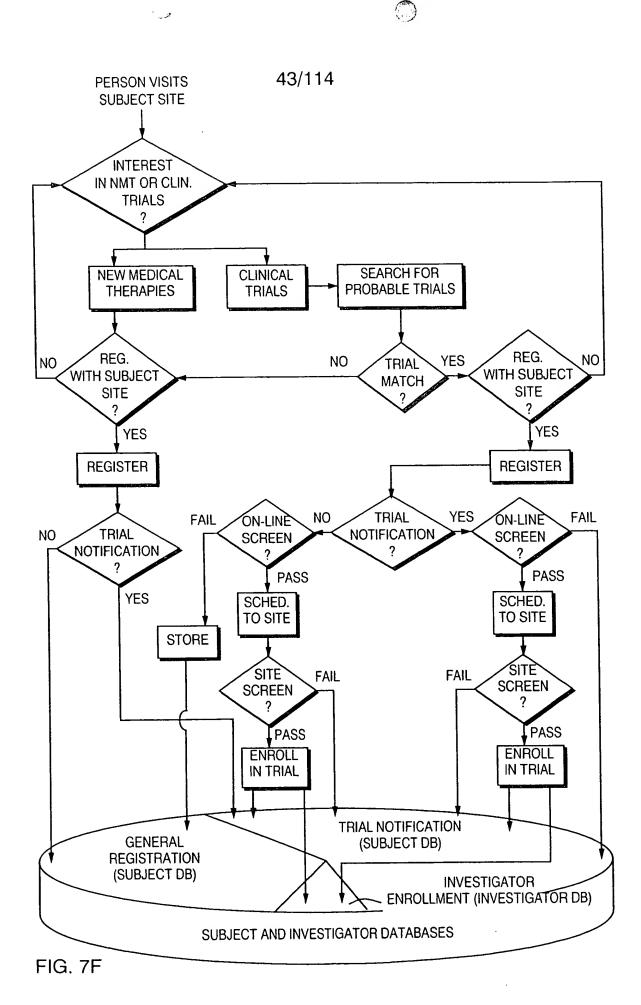


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Investigators	Local IRB 🔲 Centra IEC (Canadian sites only)		Weekly Monthly			O Yes O No
						0
How many Investigators conduct research at this PRF?*	Is the Investigator affiliated with: (check all that apply)	If affiliated with a local IRB, what is its name?	How often does the local IRB meet?	If "other", frequency of local IRB meeting?	How soon after the IRB meeting will you receive an approval letter?	Has the Investigator ever been audited by the Food & Drug Administration (FDA) or any other regulatory agency?

			602					240		$\overline{}$
		O Yes O No				O Yes O No		O Yes O No		
<ol> <li>If yes, what was the date of the audit?</li> </ol>	Who was the auditor?	If audited, was a 483 issued ?	What were the results of the audit?	<ol><li>If yes, what was the date of the audit?</li></ol>	Who was the auditor?	If audited, was a 483 issued ?	What were the results of the audit?	Has the Investigator gone through an audit by a sponsor or CRO?	<ol> <li>If yes, what was the date of the audit?</li> </ol>	Who was the auditor?

	710						711		<del>-</del>		
				<ul><li>☐ Single specialty</li><li>☐ Multi-specialty</li></ul>			Solo practice Group practice	O Yes O No		O Yes O No	Save and Continue
What were the results of the audit?	2. If yes, what was the date of the audit?	Who was the auditor?	What were the results of the audit?	ls your PRF	If PRF is multi-specialty, indicate specialties. (one per line)		Is your facility part of	Is the facility affiliated with a Site Management Organization (SMO) or research group?	If affiliated, please specify the SMO name	If affiliated, is this an exclusive relationship?	© Cancel

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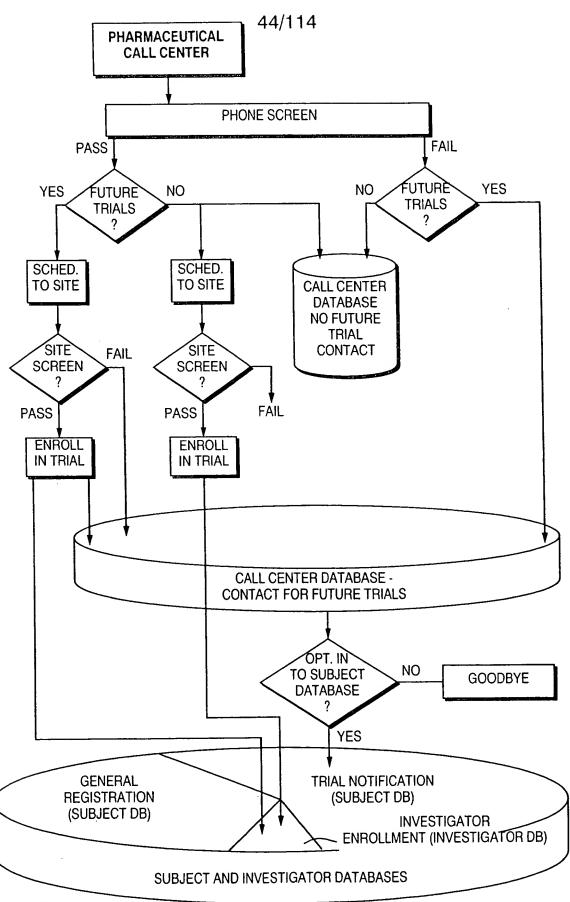
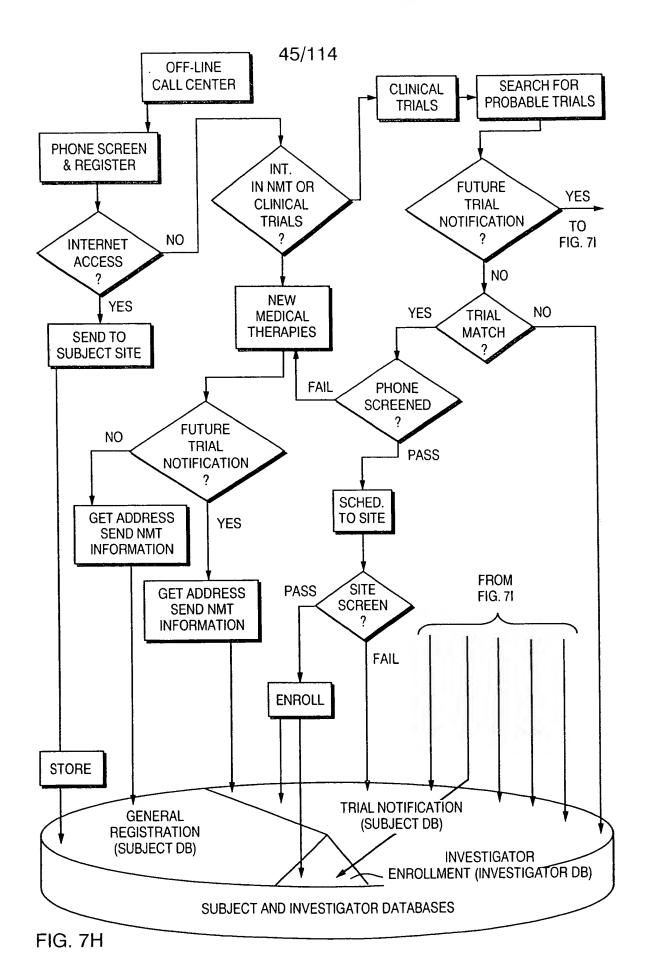


FIG. 7G







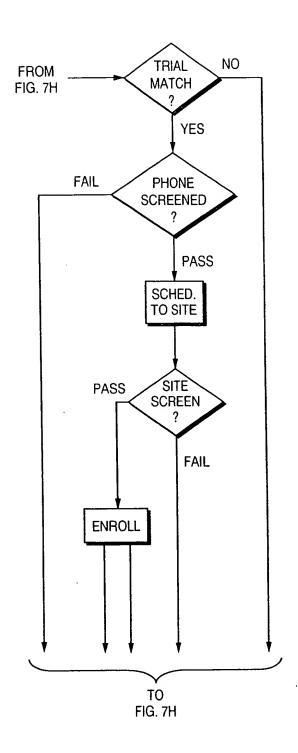


FIG. 71



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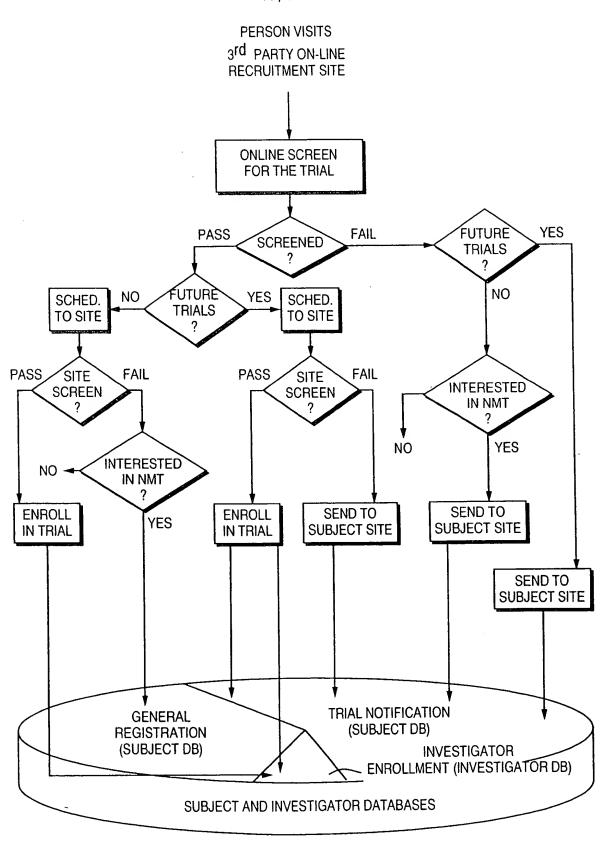


FIG. 7J

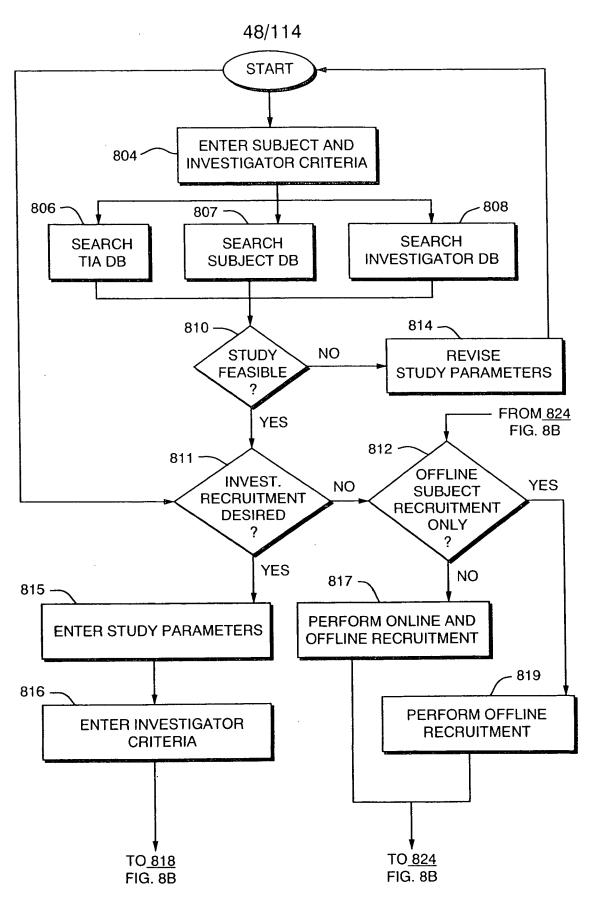


FIG. 8A



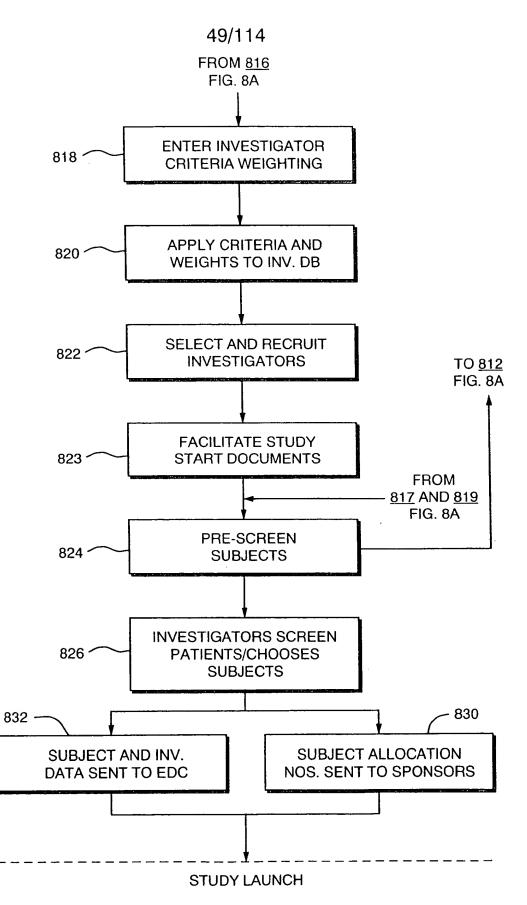
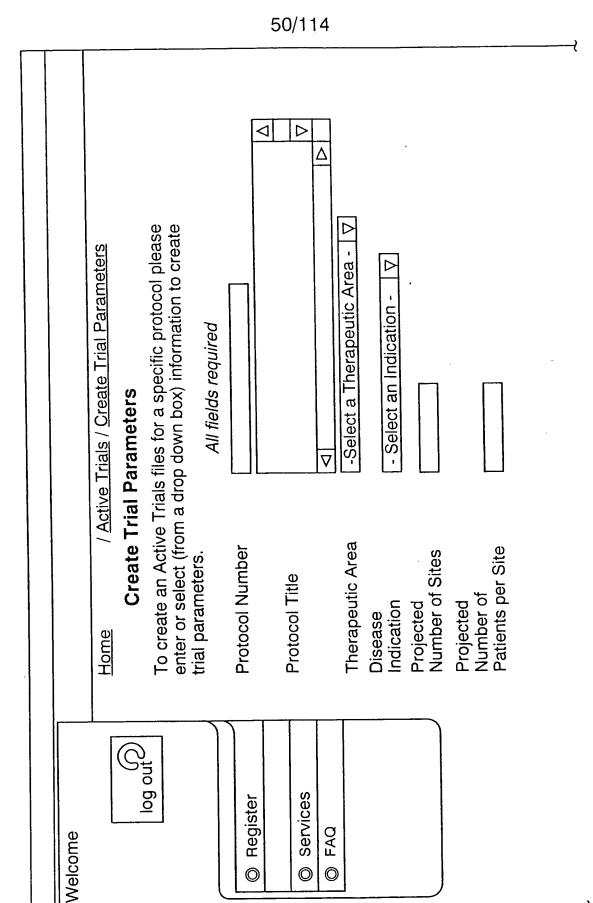


FIG. 8B



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FIG. 9A

)					
	January ∇ 2000 ∇ (Month/Year)	January [∇] 2000 [∇] (Month/Year)		- Select Trial Phase -   ▽	Save and Search for Investigators
	Projected Trial Start Date	Projected Trial Stop Date	Projected Enrollment Period (in months)	Trial Phase	Save Trial

FIG. 9B

To identify potential investigators - please select a specialty.

Step 1:

Allergy & Immunology Adolescent Medicine Aerospace Medicine Addiction Psychiatry

Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication. (optional) Step 2:

All Other Misc. Ethical Drugs - No Drug Class Aids Therapies Acne Therapy

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Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

To include the number of trials conducted by the investigator in the search, enter a number. (optional)

Step 3:





To access additional databases to enhance the investigator selection process, enter selections below. (optional)

Step 4:

### Patient Therapeutic Area



### Patient Disease Indication



# Patient Disease Indication Encounter Category

Case Load Estimates - Malignancy of heptobiliary system of pancreas Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas - Select a Category -

Note: To select more than one patient disease encounter category, point to the specialty and press control

click. Limit of 2 selections.

## Patient Distance from Site (in miles)



To limit search by geographical location - please enter your selections below.

### Municipal Area

Step 5:



FIG. 10B

Welcome	Home /	/ Active Trials / Tria	Active Trials / Trial at a Glance / Search		\
		Investigator Search Results	rch Results		\
Protocol Number 1234-5678	The following and the patie selections by Criteria Sum	investigator search res nt demographic data se scrolling down this pag <u>mary</u> . Click a column he	The following investigator search results reflect the investigator search criteria and the patient demographic data selected in the Investigator Search. Review selections by scrolling down this page or by clicking here: <u>Investigator Search Criteria Summary</u> . Click a column heading to sort by that column.	tor search criteria r Search. Review <u>/estigator Search</u> umn.	
	Displaying 1-	Displaying 1-20 out of 682 results	10/20/2		
O Register	Search Res	Results:			
	Name		City, State		
Services	Jones, J Haspiel, J	Cardiovascular Disease Cardiovascular Disease	SEATTLE, WA LA JOLLA, CA	28 28	54/
Ø FAQ	Turco, C	Cardiovascular Disease	SALT LAKE CI, UI MILWAUKEE. WI	27	1114
		Cardiovascular Disease	CINCINNATI, OH	25	1
Security &	Robinson, C Michelson, L	Cardiovascular Disease Cardiovascular Disease		24	
Privacy Policy	Kleger, B		PITTSBURGH, PA	22	
-	Doe, J	Cardiovascular Disease	SAKASOTA, FL HILLSBORO OR	70,01	
O Active Trials	Greene M	Cardiovascular Disease		<u>. 6</u>	
Create Trial			FORT WAYNE, IN	17	
	Nicholas, J Hamilton P	Cardiovascular Disease	DURHAM, NC		
	Tang, H	Cardiovascular Disease	REDONDO BEAC, CA	15	
	Wilcox, J. Singer i	Cardiovascular Disease Cardiovascular Disease	SANTA ROSA, CA	255	Ç
	Restrepo, A	Cardiovascular Disease	CHARLESTON, SC	13	- 10 티오 118
	Grossman	Cardiovascular Disease	SELLERSVILLE PA	12	<u>.</u>
FIG. 11A Next 20 >	_ ^I	Cardiovasculai Disease	000000000000000000000000000000000000000	. 7	

FROM FIG. 11A

FIG. 11B

Misc Other 6 IBB any document to go to Document View by Investigator. Click on Summary of document status for the selected protocol. Click on Other 5 any investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of | Regulatory | Financial | Vendor Info | CV/Signature Other A multi-center study ... Document Summary Other 3 Trial at a Glance Other 2 Other Trial Synopsis Conf. Agreement Active Trials / documents in that category. Questionnaire ဟ ဟ **Document Tracking** S = Sent R = Received C = Completed Robinson, M. Feasibility | Investigator egend Smith, J. Home Investigator Protocol Number Document Document Summary Services Register View View FAQ Welcome 345678 0 0 0 0 0 0

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Investigators:

Return to Trial at a Glance

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FIG 12

Regulatory | Financial | Vendor Info | CV/Signature | IRB | Misc Create New Document categories denoted by the tabs below. Click on a tab to view status of the drop down box. Study launch documents have been grouped into investigator to go to document history of the document selected in / <u>Active Trials</u> / <u>Trial at a Glance</u> / <u>Document</u> Completed 1/28/01  $Z \land X \land X \land A \land L$ Date Summary of document status by investigator. Click on any Document View by Investigator  $\triangleright$ ഗ 1/27/01 Rec'd Date Tracking / Document View by Investigator  $\alpha$ Ø ۵ 0 z S documents in that category HJKL Questionnaire Date Sent ഗ ட Investigators: ABCDE Document: Feasibility Investigator ABCD Smith, J. Home / Investigator Protocol Number Document Document Summary Services Register View View FAQ Welcome 345678 0 0 0 0 0 0

FIG. 13

From: Service Provider

Sent: June 6, 2000

To: Ms. Moore

Subject: Clinical Trial Opportunity

Dear Ms. Moore:

You may qualify for an upcoming clinical trial opportunity. For additional information go to http://www.website.com/study/zz-234567-22\* and complete the study specific questionnaire.

Contact service.com with any questions or comments you may have.

Sincerely,

Service Provider

If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to http://www.service.com/remove

FIG. 14

### Questionnaire - Alzheimer's

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant?

Yes, I am the potential study participant.

Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies.

No, I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.

- O Male O Female

How did you hear about this study? O Internet

- Newspaper Ad
- Newspaper Article
- Radio Public Service Announcement Radio Ad
- TV Ad
- TV program
  - Physician
    - Friend
- Patient Ed Materials Support Group
- Cardiology Newsletter
- Other, please specify:

daily visits from a responsible caregiver. The caregiver must be familiar with your recent medical the ability to reason, remember, imagine, and learn in humans who have already been diagnosed The purpose of this medical research study is to evaluate the effect of an investigational drug on with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive history and be willing to come to 7 doctor visits for a period of 6 months.

COSKERS CECES

person at the research facility will be calling you. At that time, it will be determined if a first After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease?

Have you experienced a deterioration in memory over at least the last 6 months?

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- O orientation
- judgement
- problem solving
- functioning in community affairs functioning in home or hobbies
  - functioning in personal care

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O Yes O Yes O Yes O Yes O No Click the box next to the person who will serve in the role of Caregiver: I am the Caregiver Friend Relative Paid personnel No Caregiver I. Please enter your date of birth:  Day Month Year (pull-down boxes)  If female, continue with question 2  If female, continue with question 46 O Yes - continue with question #3  Do you/Does (Patient) have any other neurological conditions such as: O Parkinson's disease O Huntingtons chorea O Down's syndroch isease
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O Vitamin deficiency

O Type (drop down menu)

- Brain abscess
- Syphilis
- O Meningitis O AIDS
- Brain cancer
- Thyroid, parathyroid, or pituitary disease
  - Cushing's syndrome
    - Kidney failure
- O Uncontrolled diabetes O Mental retardation
- Do you have a history of any of the following: Ś.
- Stroke within the past 12 months
- Epilepsy or convulsions (Childhood convulsions caused by fever continue) O Stroke within the p O Epilepsy or convul. O Major depression
- Stomach ulcer that is currently being treated
  - Liver, kidney, or lung disease
    - Kidney stones
- Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months? 6.
- O No Yes

Do you experience angina (chest pain) that required a change in medication in the past 3 months? 7.

S X es

Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute? ∞:

O Yes O No

Do you take medication for high blood pressure or chronic low blood pressure?

O Yes

O Medication(s) taken: (drop down menu) 6

O No O Don't know

10. Do you take any medications for the purpose of treating memory loss such as dementia?

O Yes O No

11. Are you allergic to any medications?

O Yes O Which Medication(s) (drop down menu)

° O

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Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba? 12.

O Yes O Which Medication(s) (drop down menu)

Have you ever been enrolled in a research study for galantamine? 13.

**(19** 

O Yes O No O Don't know

Have you taken an investigational drug in the past 30 days or are you taking one now? 14.

O No, I have not taken an investigational drug in the past 30 days

O Yes, I have taken an investigational drug in the past 30 days O Yes, I am taking an investigational drug now

How many drinks do you consume in a typical 24-hour period? 15.

O 1-2 drinks
O 3-5 drinks
O 6-8 drinks
O more than 8 drinks

Have you/patient had a CT scan or MRI of the head during the last 12 months? 16.

O Yes O Ro

Questionnaire - Alzheimer's

PATIENT NOT ELIGIBLE FOR STUDY SCREEN #2:

provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies? We appreciate your interest in this study. Unfortunately, from the information you have

O Yes, contact me. O No, I do not want to be contacted.

FIG. 15G



### Questionnaire - Alzheimer's

### PATIENT POTENTIALLY ELIGIBLE FOR STUDY: SCREEN #3:

information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5-7 business days, please feel free to call the Based on your responses, you may be eligible for the clinical study. We will forward this number that will be included in your mailed materials.

In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies?

- O Yes, contact me O No, I do not want to be contacted

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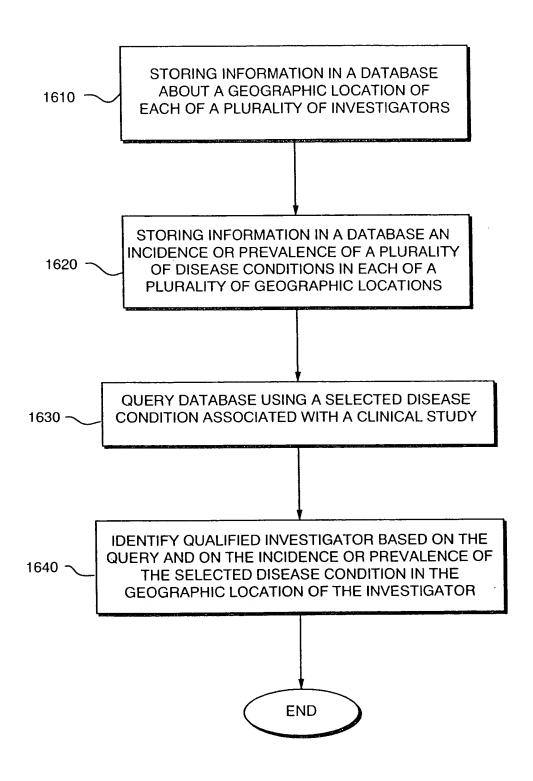


FIG. 16

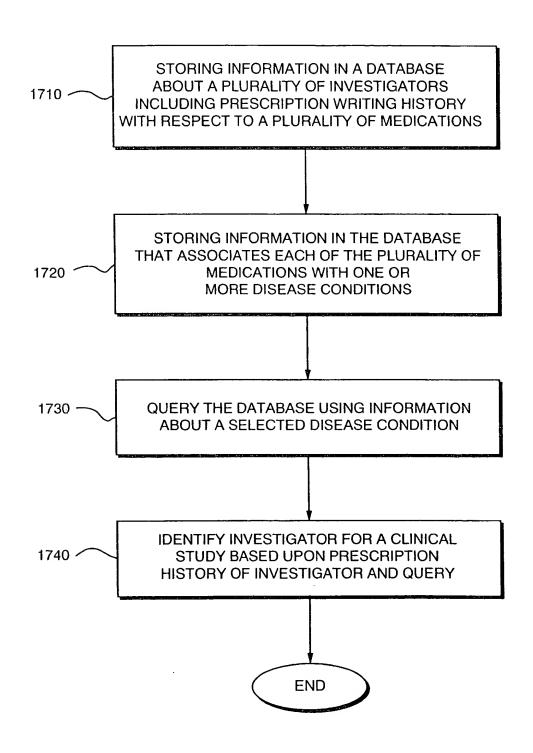


FIG. 17

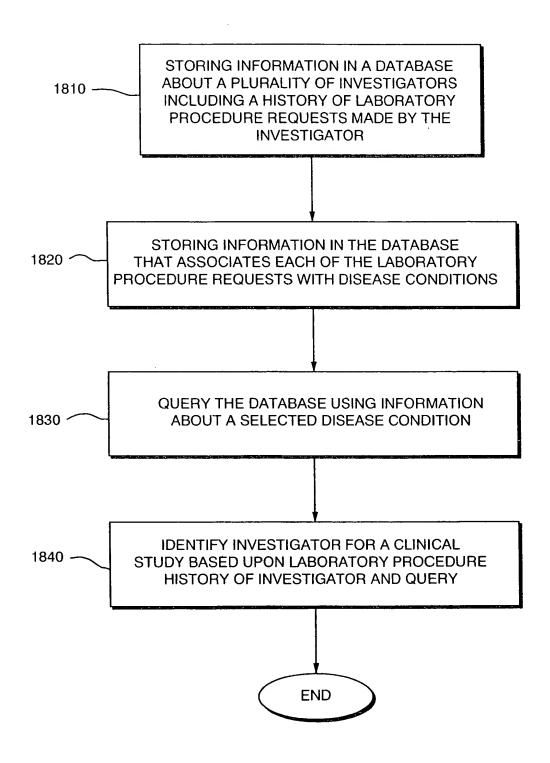


FIG. 18

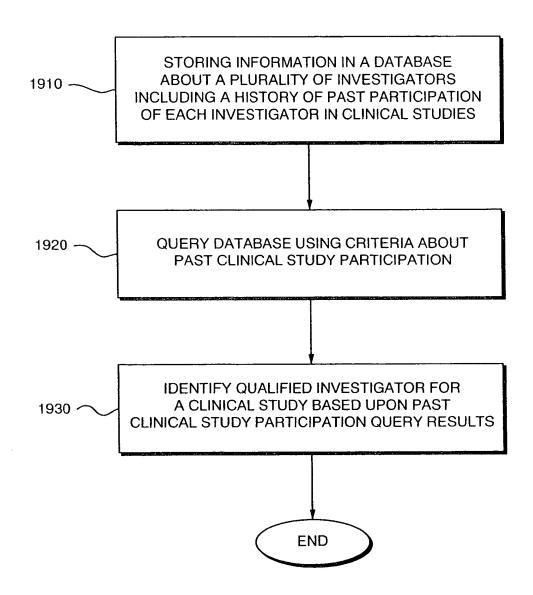


FIG. 19

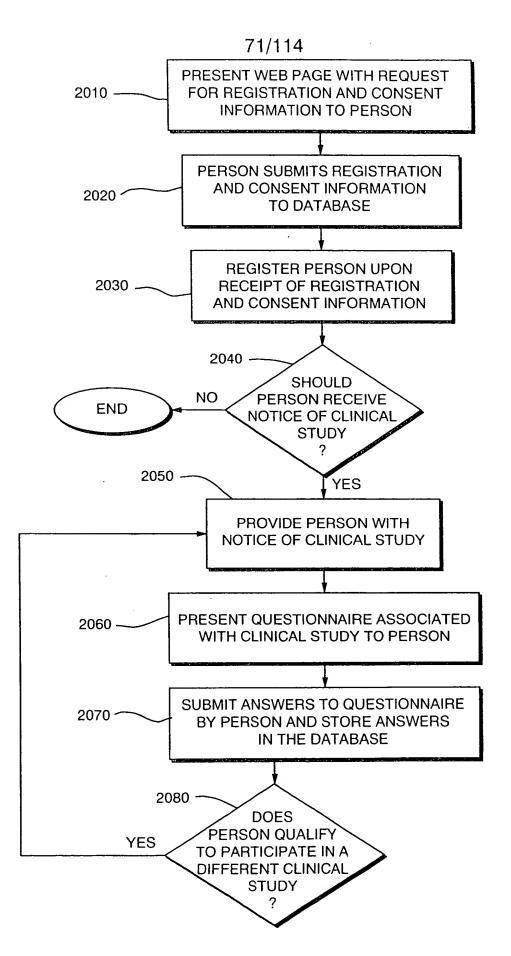


FIG. 20

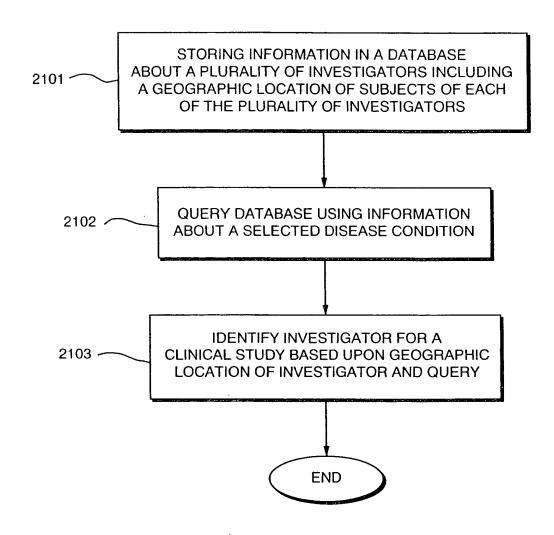


FIG. 21A

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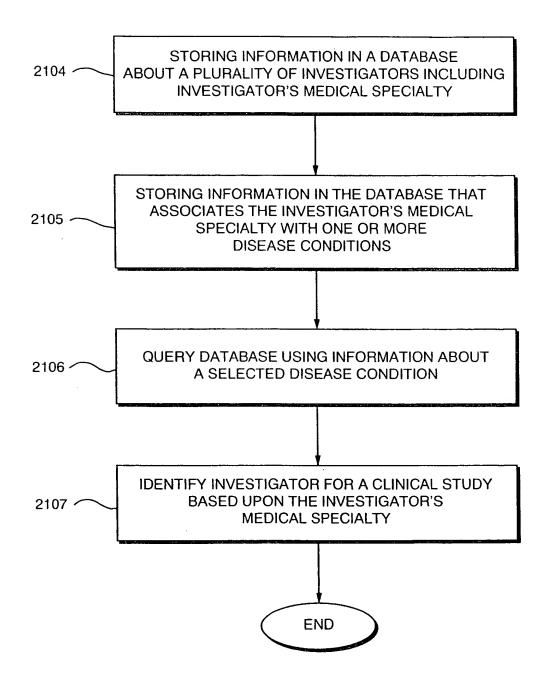


FIG. 21B



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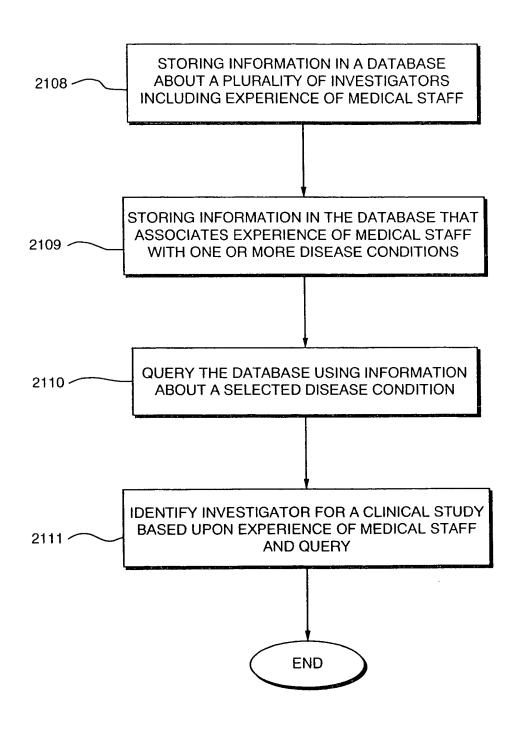


FIG. 21C

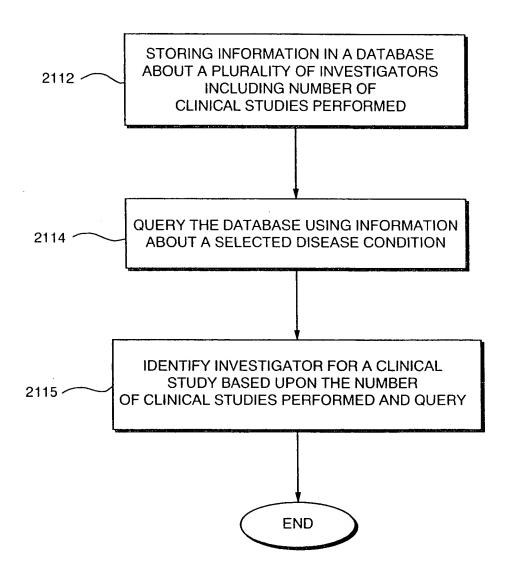


FIG. 21D



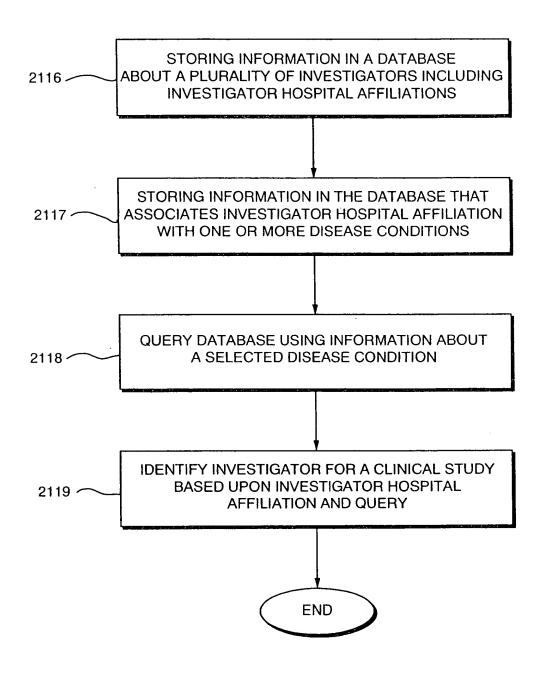


FIG. 21E



" 22.7

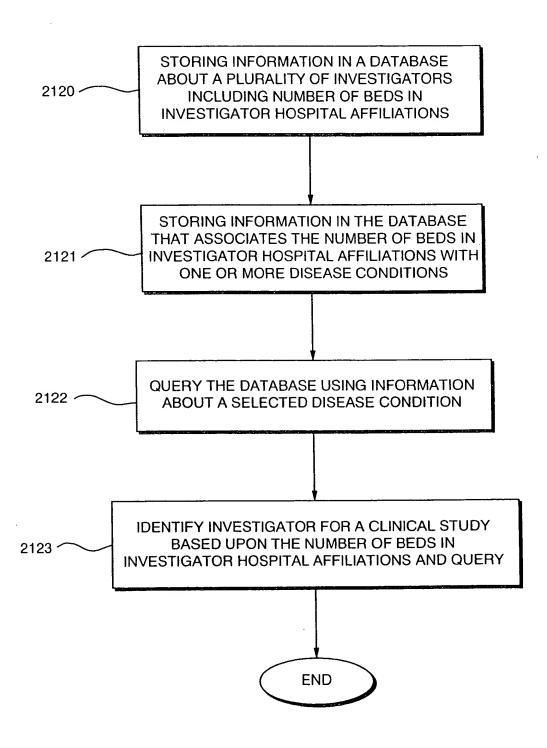


FIG. 21F

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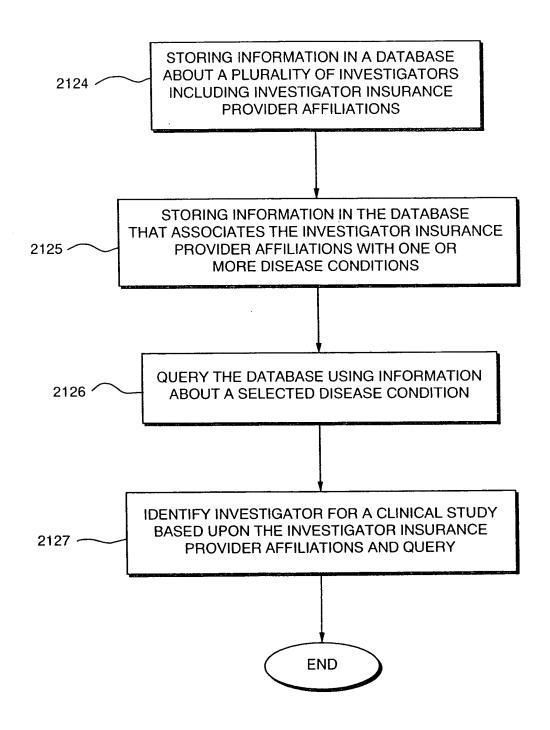


FIG. 21G



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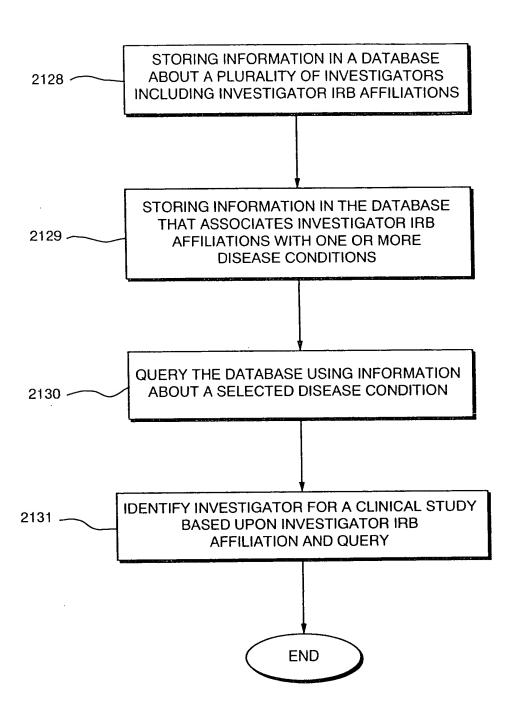


FIG. 21H



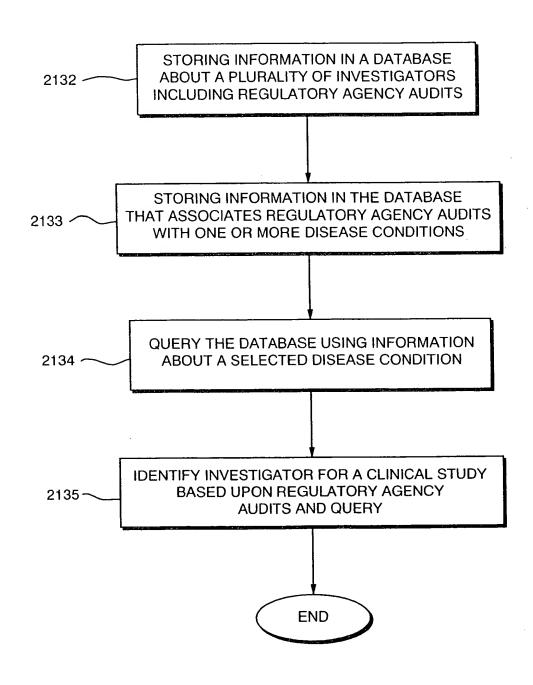


FIG. 211

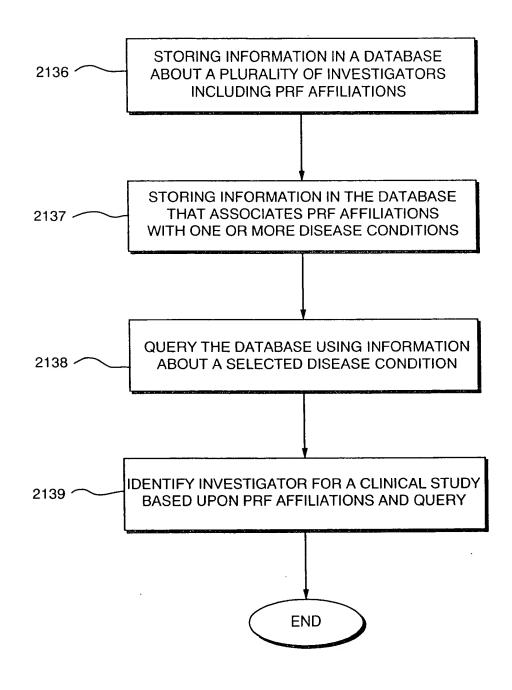


FIG. 21J



. 27

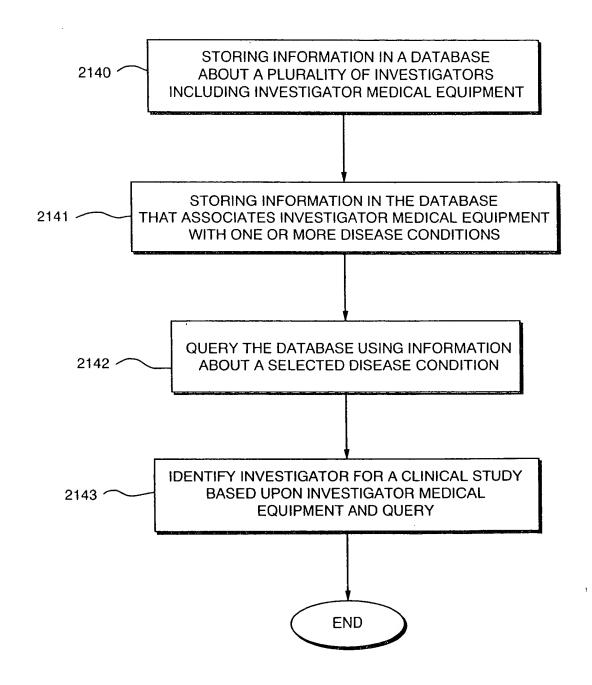


FIG. 21K



5.30

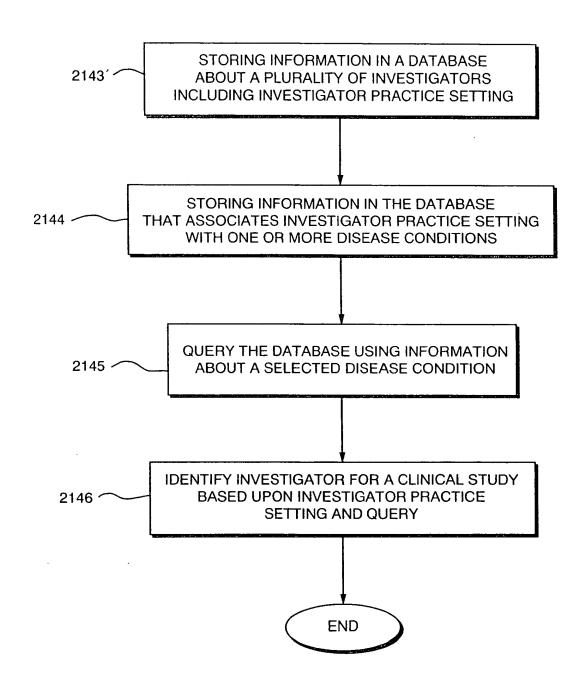


FIG. 21L

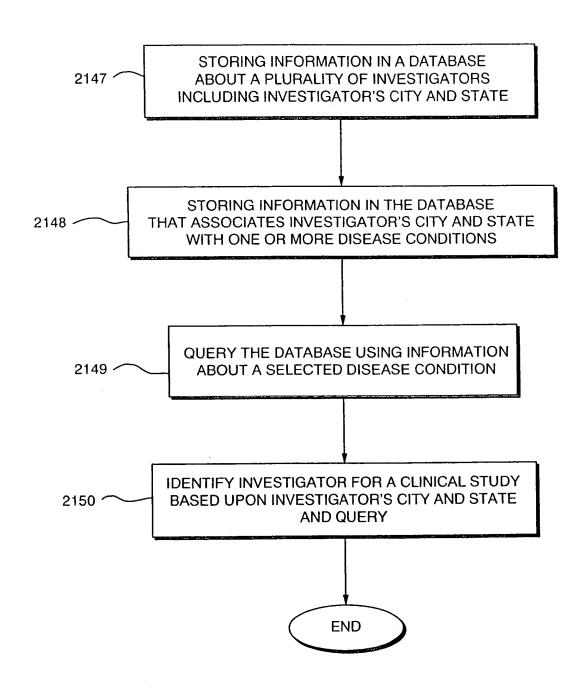


FIG. 21M

Cont

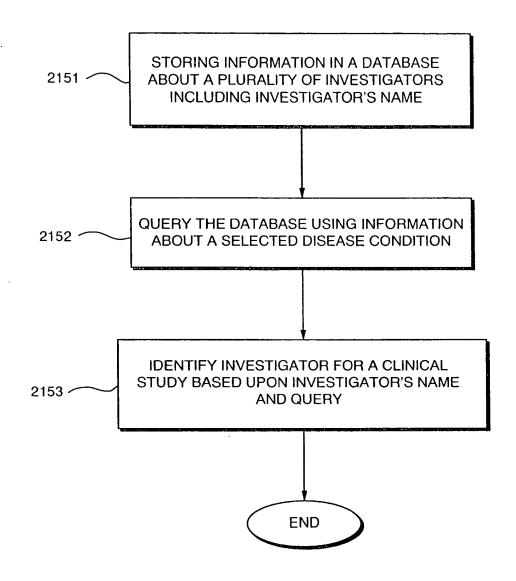


FIG. 21N

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1

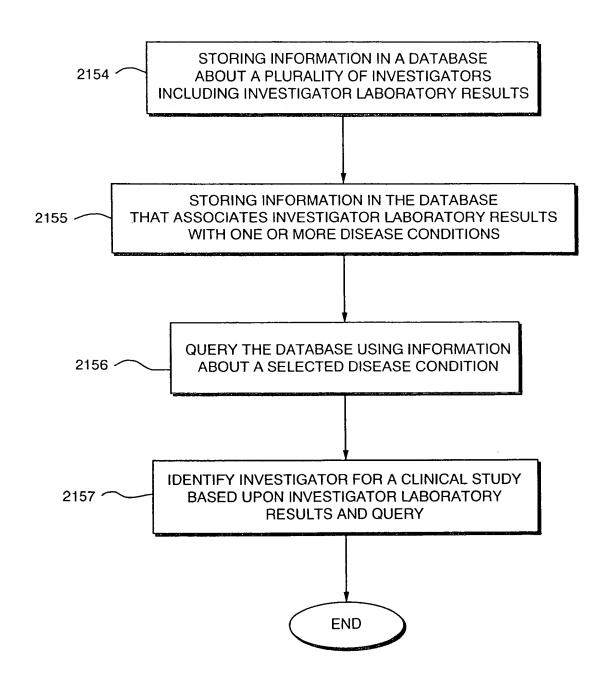


FIG. 210

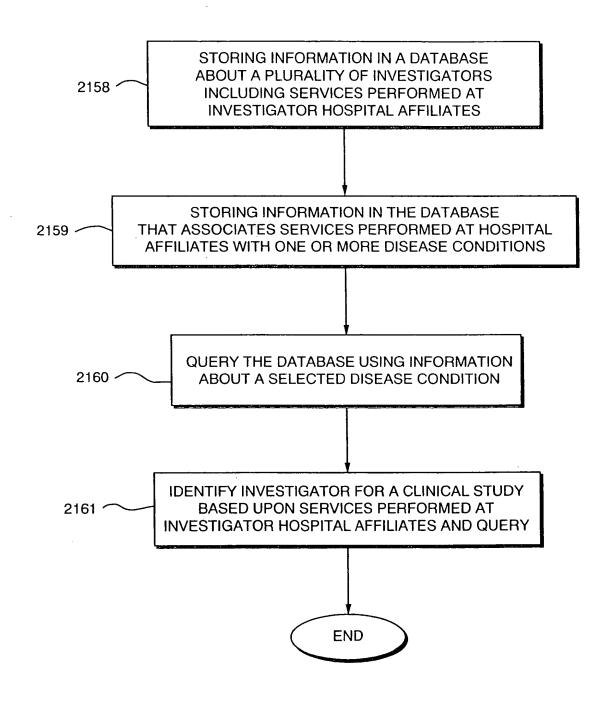


FIG. 21P

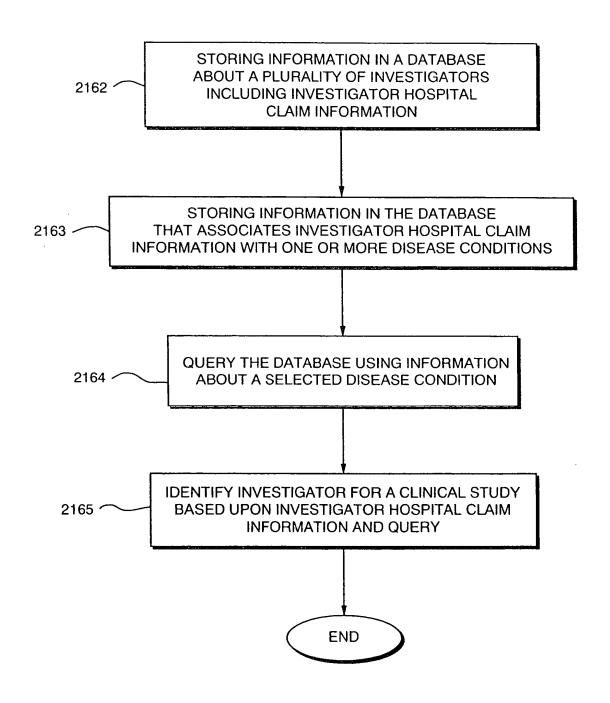
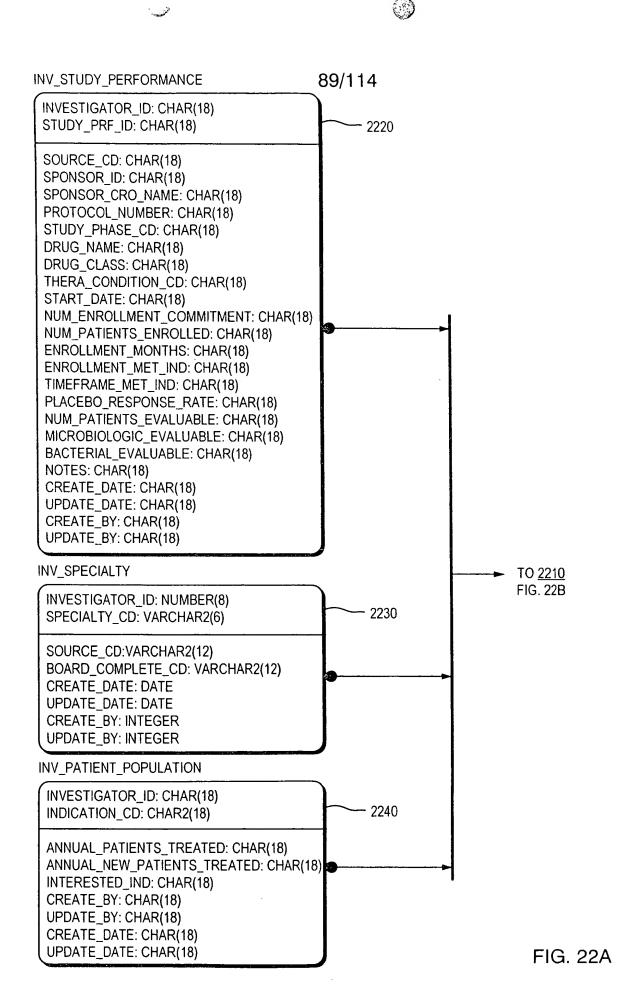


FIG. 21Q



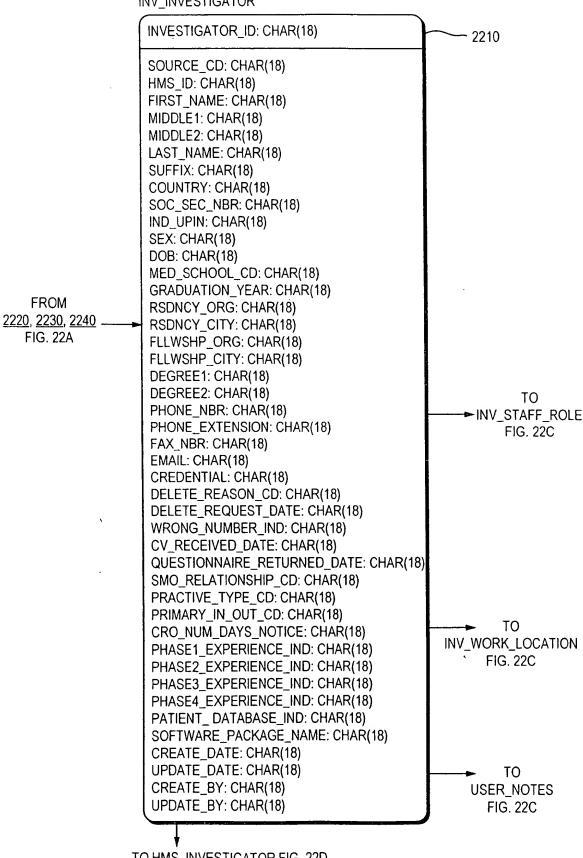
**FROM** 

FIG. 22A





#### 90/114 INV\_INVESTIGATOR



TO HMS\_INVESTIGATOR FIG. 22D

FIG. 22B

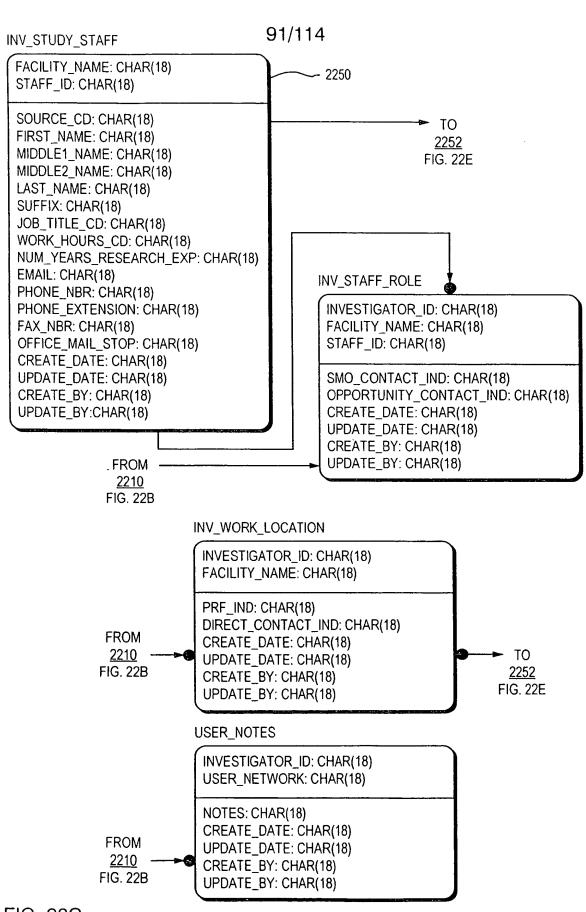
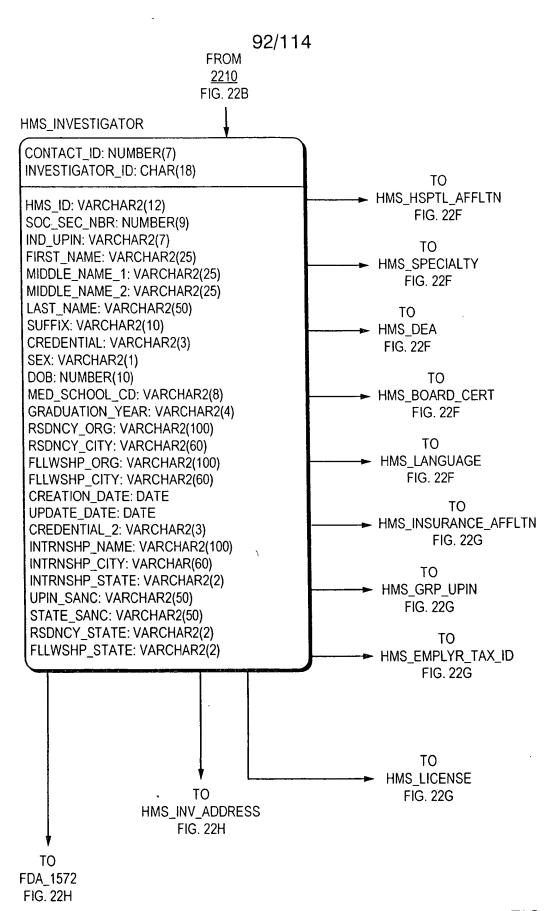


FIG. 22C





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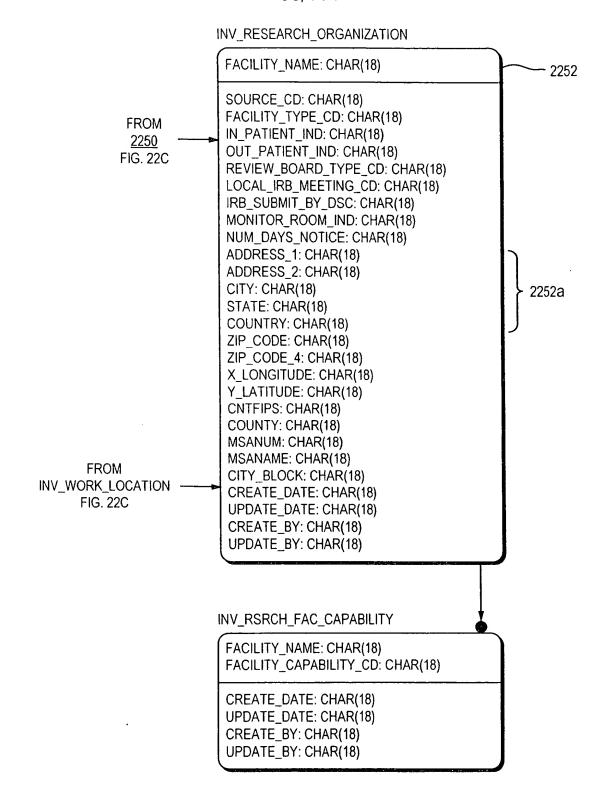


FIG. 22E

1

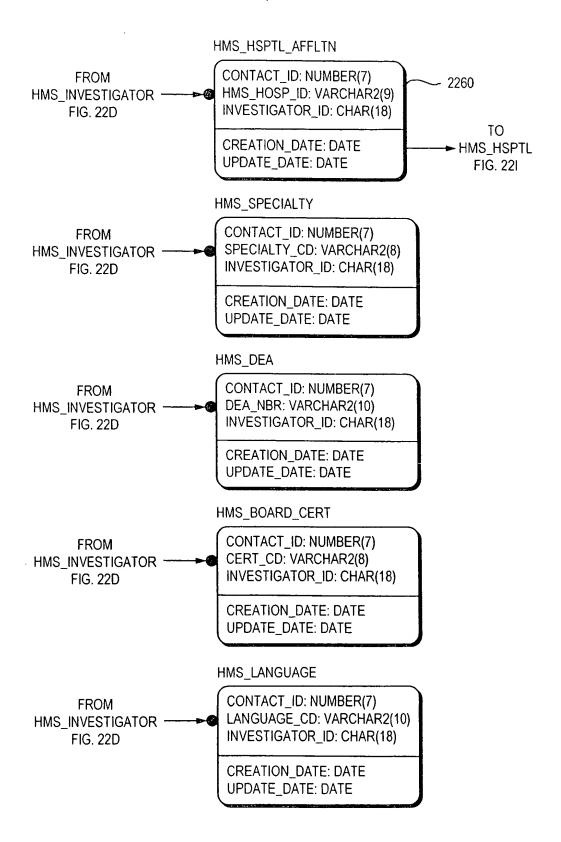
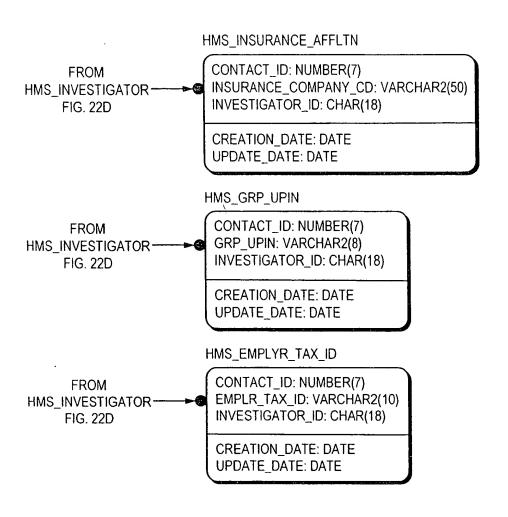


FIG. 22F

(1)



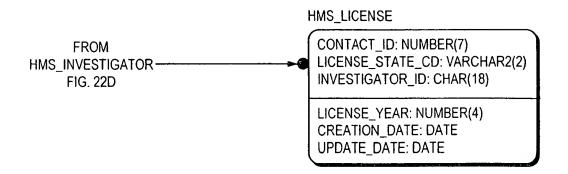


FIG. 22G



## FROM HMS INVESTIGATOR

FIG. 22D

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FROM HMS\_INVESTIGATOR FIG. 22D

#### FDA 1572

CONTACT ID: NUMBER(7) FDA\_1572\_ID: NUMBER(7) INVESTIGATOR\_ID: CHAR(18)

HMS\_ID: VARCHAR2(12) LAST NAME: VARCHAR2(100) FIRST\_NAME: VARCHAR2(25) MIDDLE\_INITIAL: VARCHAR2(1)

SUFX: VARCHAR2(5) CRED1: VARCHAR2(8) ORGNAME: VARCHAR2(100) ADDRESS: VARCHAR2(100) CITY: VARCHAR2(35) STATE: VARCHAR2(2) ZIP CODE: NUMBER(14) COUNTRY: VARCHAR2(60) YEAR: NUMBER(4)

RECEIPT DATE: DATE RECEIPT\_YEAR: NUMBER(4) ORG\_TYPE: VARCHAR2(3) CREATION\_DATE: DATE

HMS INV ADDRESS

CONTACT\_ID: NUMBER(7) ADDRESS ID: NUMBER(6) INVESTIGATOR\_ID: CHAR(18)

HMS\_ID: VARCHAR2(12)

TIER: NUMBER(3) FIRM\_NAME: VARCHAR2(100) ADDRESS\_1: VARCHAR2(75) ADDRESS\_2: VARCHAR2(75) PHONE\_NBR: NUMBER(15) FAX\_NBR: NUMBER(15) CITY: VARCHAR2(35) STATE: VARCHAR2(2) ZIP\_CODE: NUMBER(10) ZIP CODE 4: NUMBER(4) X LONGITUDE: NUMBER(15)

Y\_LATITUDE: NUMBER(15) MSANUM: NUMBER(12) MSANAME: VARCHAR2(45) COUNTY: VARCHAR2(30) CNTFIPS: NUMBER(12)

CITY\_BLOCK: VARCHAR2(30) CREATION\_DATE: DATE UPDATE\_DATE: DATE

#### FDA 483

CONTACT\_ID: NUMBER(7) FDA\_DFCNCY\_ID: NUMBER(8) CONTACT\_ID: NUMBER(7) INVESTIGATOR\_ID: CHAR(18)

HMS\_ID: VARCHAR2(12) LAST\_NAME: VARCHAR2(100) FIRST\_NAME: VARCHAR2(25) ORG: VARCHAR2(100)

ADDRESS: VARCHAR2(100) CITY: VARCHAR2(35) STATE: VARCHAR2(2) ZIP\_CODE: NUMBER(14)

COUNTRY: VARCHAR2(60) INSPCTN\_DATE: DATE

CLSSFCTN\_TYP: VARCHAR2(2) CLSSFCTN\_CD: VARCHAR2(5) DFCNCY\_CD: NUMBER(2) CREATION DATE: DATE

FDA\_1572\_STAT

CONTACT\_ID: NUMBER(8) INVESTIGATOR ID: CHAR(18)

NUM\_TRIALS\_LAST5: INTEGER NUM\_TRIALS\_LAST4: INTEGER NUM\_TRIALS\_LAST3: INTEGER NUM\_TRIALS\_LAST2: INTEGER NUM TRIALS LAST1: INTEGER TOTAL\_TRIALS\_LIFETIME: INTEGER

FIRST\_YEAR: INTEGER LAST\_YEAR: INTEGER UPDATE\_DATE: DATE

FIG. 22H



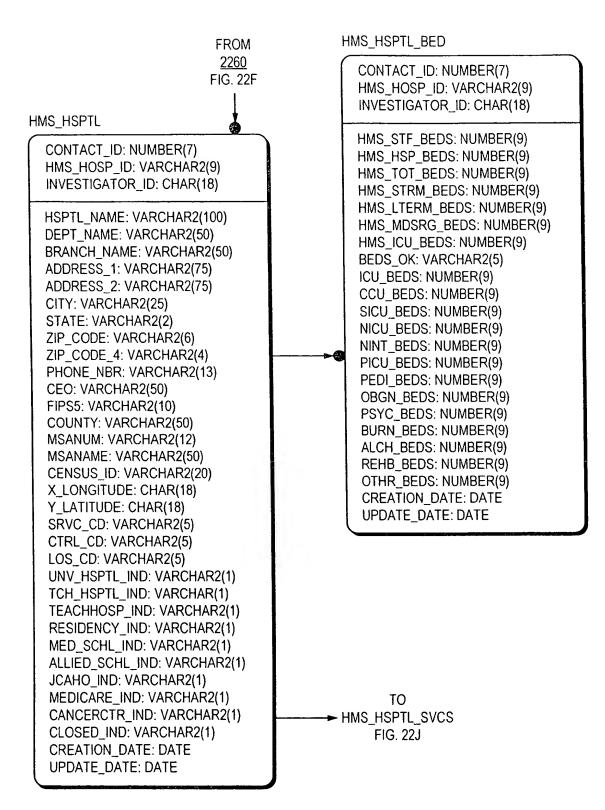


FIG. 221



#### HMS\_HSPTL\_SVCS

CONTACT\_ID: NUMBER(7)
HMS\_HOSP\_ID: VARCHAR2(9)
INVESTIGATOR\_ID: CHAR(18)

AIDS\_SVCS: VARCHAR2(1)
ANSTH\_SVCS: VARCHAR2(1)
ANGPLSTY\_SVCS: VARCHAR(1)
BLOODBNK\_SVCS: VARCHAR(1)
BMTRNSPL\_SVCS: VARCHAR2(1)
BURNCTR\_SVCS: VARCHAR2(1)
CRDCTH\_SVCS: VARCHAR2(1)
CVSRGY\_SVCS: VARCHAR2(1)
CHIRO\_SVCS: VARCHAR2(1)
CLPSY\_SVCS: VARCHAR2(1)
CT\_SVCS: VARCHAR2(1)
ULTRSND\_SVCS: VARCHAR2(1)

FROM HMS\_HSPTL —

FIG. 22I

DIETRTY\_SVCS: VARCHAR2(1)

ECARD\_SVCS: VARCHAR2(1)

ECONV\_SVCS: VARCHAR2(1)

EMRGCY\_SVCS: VARCHAR2(1)

ESWI\_SVCS: VARCHAR2(1)

ECARD SVCS: VARCHAR2(1) ECONV\_SVCS: VARCHAR2(1) **EMRGCY SVCS: VARCHAR2(1)** ESWL\_SVCS: VARCHAR2(1) LABAN\_SVCS: VARCHAR2(1) HEART\_SVCS: VARCHAR2(1) HRTLUNG\_SVCS: VARCHAR2(1) HEMDIAL\_SVCS: VARCHAR2(1) HOMCRE\_SVCS: VARCHAR2(1) **HOSPCE SVCS: VARCHAR2(1)** CCU\_SVCS: VARCHAR2(1) ICU\_SVCS: VARCHAR2(1) KIDNEY\_SVCS: VARCHAR2(1) LABCLNC\_SVCS: VARCHAR2(1) LIVER\_SVCS: VARCHAR2(1) LUNG SVCS: VARCHAR2(1) MEGVRAD\_SVCS: VARCHAR2(1) NEONUNT\_SVCS: VARCHAR2(1) NICU\_SVCS: VARCHAR2(1) MRI\_SVCS: VARCHAR2(1) **NEURO SVCS: VARCHAR2(1) NSURG SVCS: VARCHAR2(1)** NUCMED SVCS: VARCHAR2(1) **OBSRVA SVCS: VARCHAR2(1) OBSTE SVCS: VARCHAR2(1)** OCCTH\_SVCS: VARCHAR2(1) OPNHT SVCS: VARCHAR2(1)

TO FIG. 22K

#### HMS\_HSPTL\_SVCS (CONT'D)

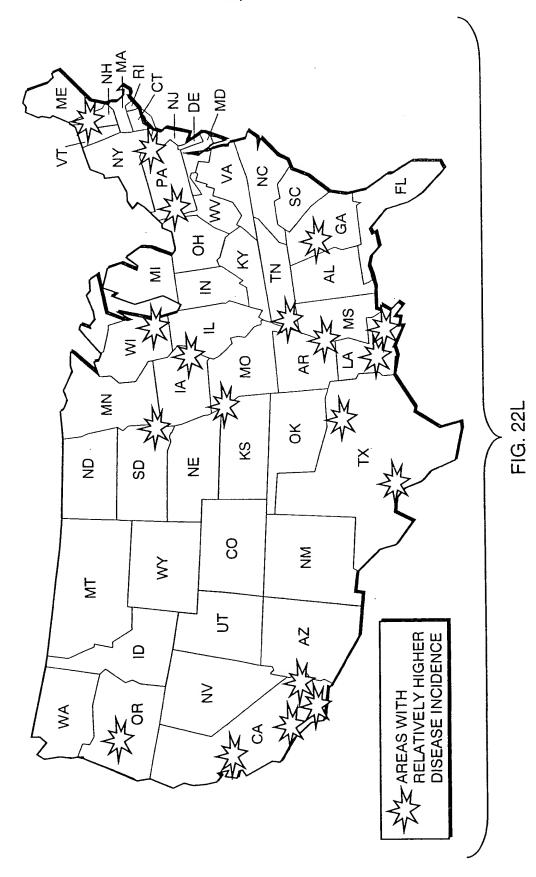
FROM FIG. 22J

OPTOM\_SVCS: VARCHAR2(1) ORGBANK\_SVCS: VARCHAR2(1) ORGAN\_SVCS: VARCHAR2(1) OUTPAT\_SVCS: VARCHAR2(1) OUTSRG\_SVCS: VARCHAR2(1) PANCR\_SVCS: VARCHAR2(1) PEDIAT\_SVCS: VARCHAR2(1) PHARM\_SVCS: VARCHAR2(1) PHYTH SVCS: VARCHAR2(1) PSTOP\_SVCS: VARCHAR2(1) PSYED SVCS: VARCHAR2(1) PULMON\_SVCS: VARCHAR2(1) RADIM\_SVCS: VARCHAR2(1) RECTH\_SVCS: VARCHAR2(1) REHAB\_SVCS: VARCHAR2(1) RESPIR\_SVCS: VARCHAR2(1) SELFCARE\_SVCS: VARCHAR2(1) SKNLT\_SVCS: VARCHAR2(1) SOCSVC\_SVCS: VARCHAR2(1) SPEECH\_SVCS: VARCHAR2(1) THERD\_SVCS: VARCHAR2(1) TRAUMA\_SVCS: VARCHAR2(1) XRADT\_SVCS: VARCHAR2(1) CREATION\_DATE: DATE UPDATE\_DATE: DATE

FIG. 22K







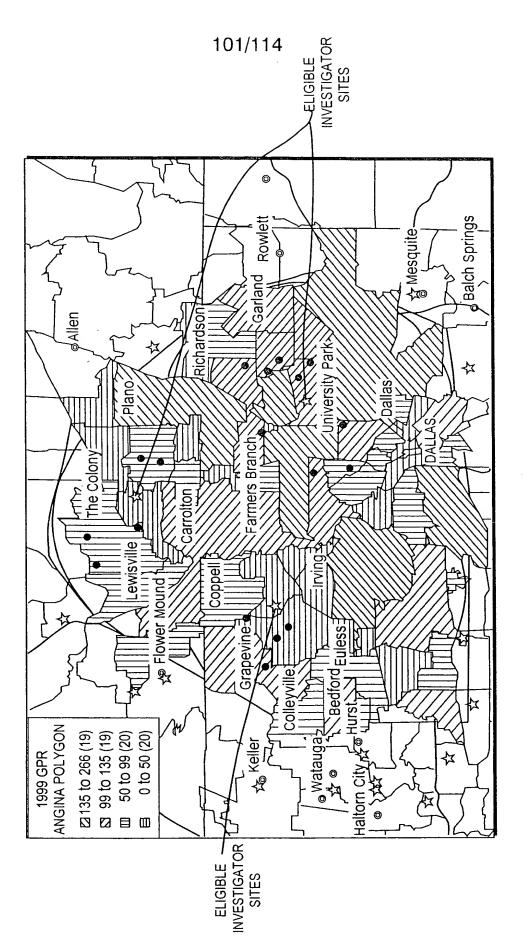


FIG. 22N

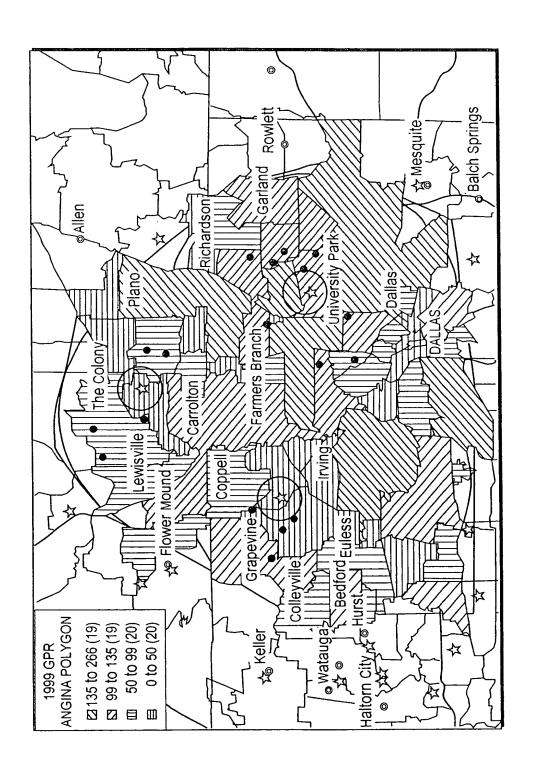


FIG. 22N

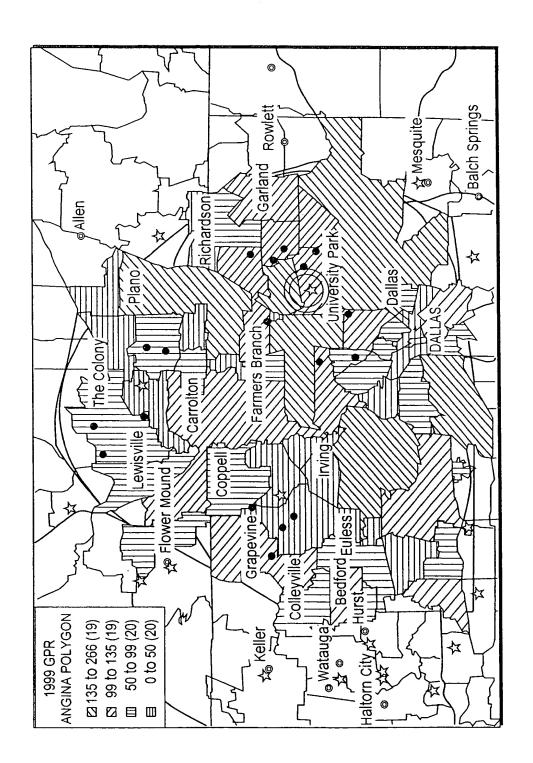
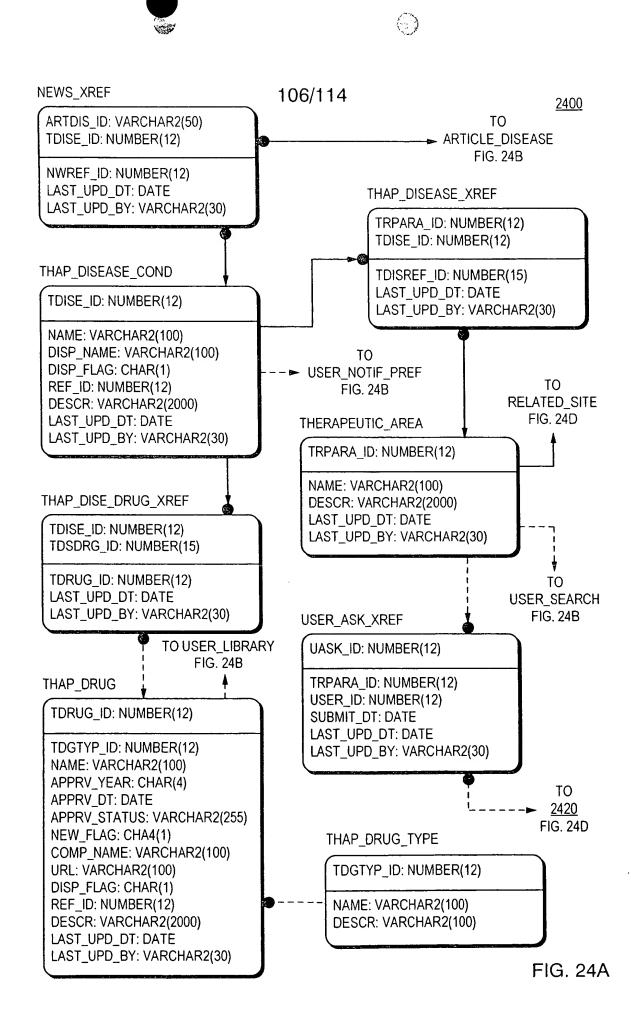


FIG. 22C

FIG. 23





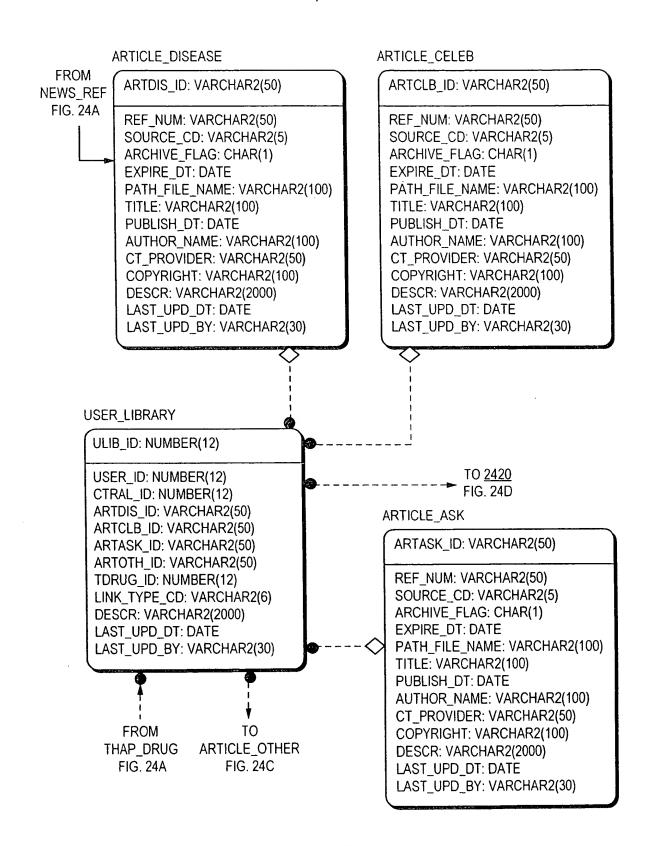


FIG. 24B



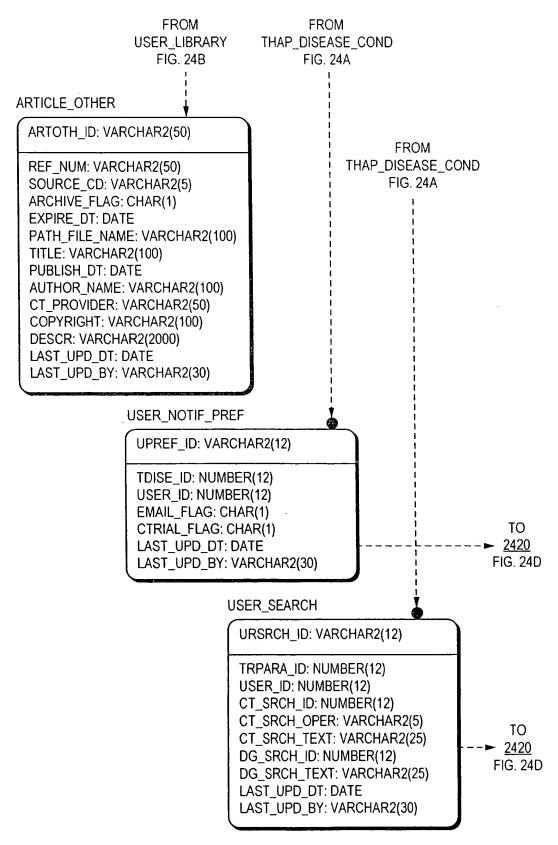


FIG. 24C

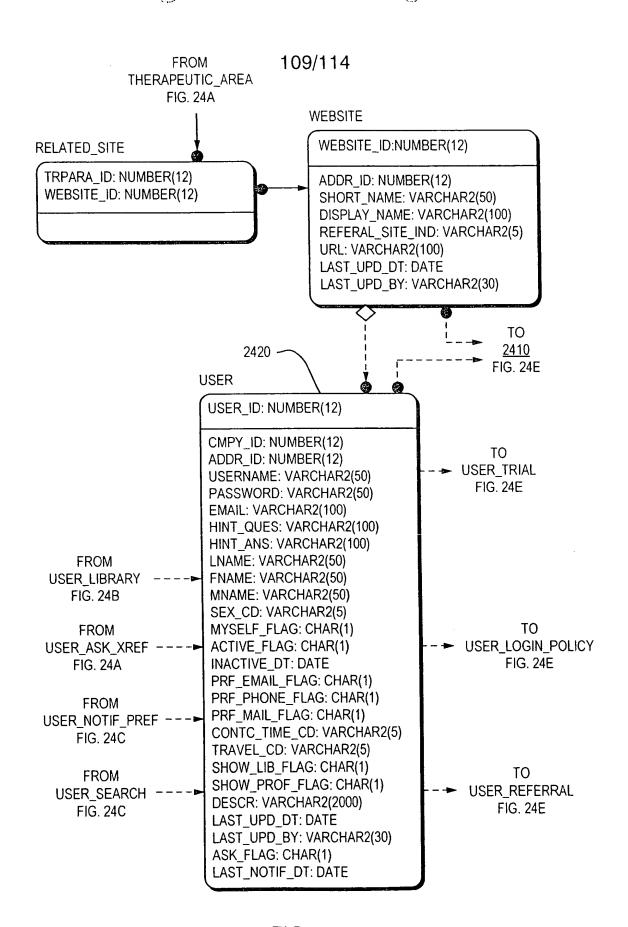


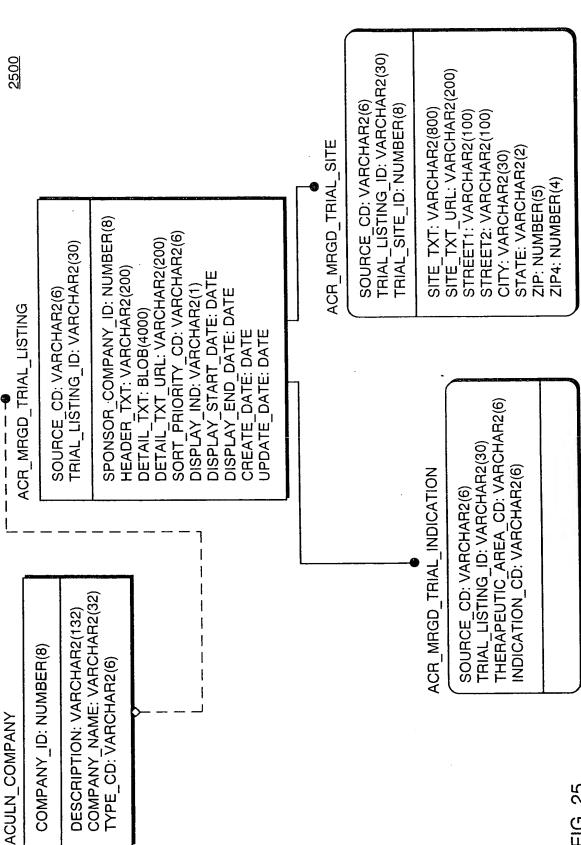
FIG. 24D



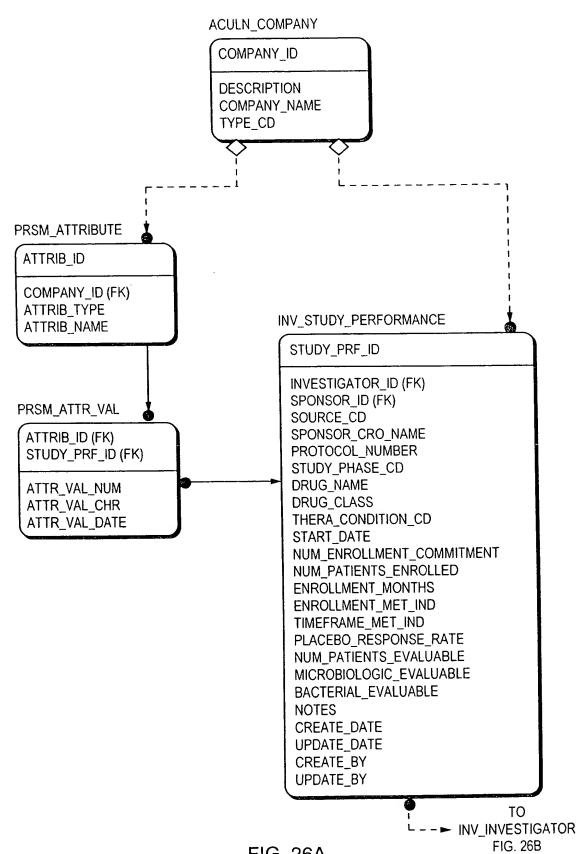
#### 110/114 **ADDRESS** ADDR\_ID: NUMBER(12) USER\_TRIAL ADDR\_LINE1: VARCHAR2(50) **FROM** USTRL\_ID:NUMBER(12) WEBSITE-ADDR LINE2: VARCHAR2(50) ADDR\_LINE3: VARCHAR2(50) FIG. 24D ADDR\_ID: NUMBER(12) CITY: VARCHAR2(50) USER\_ID: NUMBER(12) STATE CD: VARCHAR2(5) **FROM** EMAIL\_FLAG: CHAR(1) ZIP CODE: VARCHAR2(10) <u> 2420</u> PHONE FLAG: CHAR(1) PROVINCE: VARCHAR2(50) FIG. 24D MAIL\_FLAG: CHAR(1) COUNTRY: VARCHAR2(15) LNAME: VARCHAR2(50) PHONE1\_AREA: VARCHAR2(10) FNAME: VARCHAR2(50) PHONE1\_NUM: VARCHAR2(10) EMAIL: VARCHAR2(100) PHONE1\_EXT: VARCHAR2(10) 2410 DESCR: VARCHAR2(2000) PHONE2\_AREA: VARCHAR2(10) LAST\_UPD\_DT: DATE PHONE2\_NUM: VARCHAR2(10) LAST\_UPD\_BY: VARCHAR2(30) PHONE2 EXT: VARCHAR2(10) CTRAL\_ID: NUMBER(12) LAST\_UPD\_DT: DATE LAST UPD BY: VARCHAR2(30) **FROM** USER\_LOGIN\_POLICY 2420 FIG. 24D URPCY\_ID:NUMBER(12) ACURIAN CONTENT\_TYPE **FROM** USER\_ID: NUMBER(12) 2420 LOGIN\_COUNT: NUMBER(5) FIG. 24D CONTYP\_ID: NUMBER(12) ALLOW\_LOGIN\_DT: DATE RECOVERY\_COUNT: NUMBER(5) NAME: VARCHAR2(100) RECOVERY\_KEY: VARCHAR2(100) DESCR: VARCHAR2(100) RECOVERY\_ALLOW\_DT: DATE RECOVERY\_DT: DATE ACURIAN\_NOTIFICATION PASSWD\_UPD\_DT: DATE LAST UPD\_DT: DATE NOTIF\_ID:NUMBER(12) LAST UPD BY: VARCHAR2(30) CURRENT\_LOGIN\_DT: DATE NOTIF\_TYPE: VARCHAR2(100) LAST LOGIN DT: DATE NOTIF\_DESC.: VARCHAR2(100) LAST\_NOTIF\_DT: DATE USER\_REFERRAL URFAL\_ID:NUMBER(12) ACURIAN\_PUBLISH **FROM** USER\_ID: NUMBER(12) 2420 EMAIL: VARCHAR2(100) FIG. 24D PUBLISH\_ID: NUMBER(12) LAST\_UPD\_DT: DATE CONTYP\_ID: NUMBER(12) LAST UPD BY: VARCHAR2(30) PUBLISH\_DATE: DATE TRPARA ID: NUMBER(12)

FIG. 24E

LOGELLES. CECEL







**FIG. 26A** 

#### INV\_INVESTIGATOR

#### INVESTIGATOR\_ID

SOURCE\_CD

HMS\_ID

FIRST\_NAME

MIDDLE1

MIDDLE2

LAST\_NAME

**SUFFIX** 

COUNTRY

SOC\_SEC\_NBR

IND\_UPIN

SEX

DOB

MED\_SCHOOL\_CD

GRADUATION\_YEAR

RSDNCY\_ORG

RSDNCY\_CITY

FLLWSHP\_ORG

FLLWSHP\_CITY

DEGREE1

DEGREE2

PHONE\_NBR

THONE\_NON

PHONE\_EXTENSION

FAX\_NBR

**EMAIL** 

CREDENTIAL

DELETE\_REASON\_CD

DELETE\_REQUEST\_DATE

WRONG\_NUMBER\_IND

CV\_RECEIVED\_DATE

QUESTIONNAIRE\_RETURNED\_DATE

SMO\_RELATIONSHIP\_CD

PRACTIVE\_TYPE\_CD

PRIMARY\_IN\_OUT\_CD

CRO\_NUM\_DAYS\_NOTICE

PHASE1\_EXPERIENCE\_IND

PHASE2\_EXPERIENCE\_IND

PHASE3\_EXPERIENCE\_IND

PHASE4\_EXPERIENCE\_IND

PATIENT\_ DATABASE\_IND

SOFTWARE\_PACKAGE\_NAME

CREATE\_DATE

UPDATE\_DATE

CREATE\_BY

UPDATE\_BY

FIG. 26A

**FROM** 

INV\_STUDY\_PERFORMANCE -

114/114

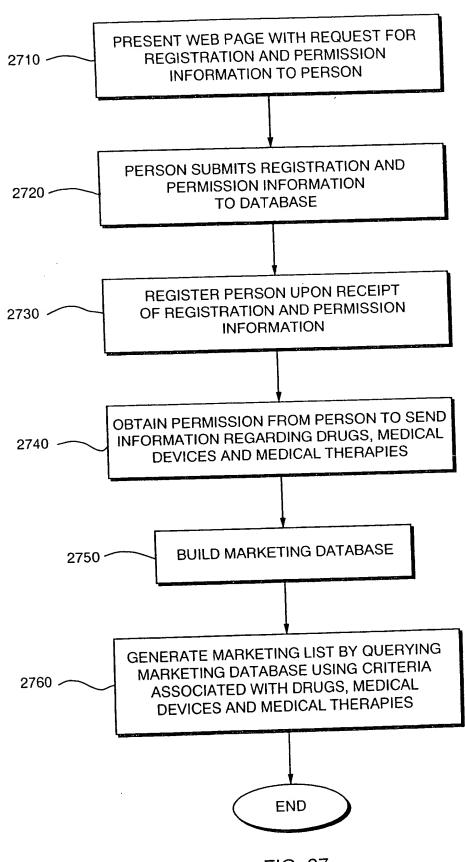


FIG. 27